No. 95-477

Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1995

NOVOPHARM LTD.,

Petitioner,

v.

GLAXO, INC. and GLAXO GROUP LIMITED,

Respondents.

Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Whether Novopharm's right of Due Process was violated (1) when the district court denied Novopharm any discovery on the issue of whether the patent-in-suit was invalid under 35 U.S.C. § 112 for failure to disclose the best mode, and then held that Novopharm had failed to prove a best mode violation and (2) when the Court of Appeals for the Federal Circuit relied on a non-evidence Declaration, as to which Novopharm was not allowed any discovery or cross-examination of the declarant, to affirm the district court holding.

Whether the panel majority erred in overruling case precedent followed by a different panel during the pendency of the present appeal.

Whether, under § 112, a best mode violation can be found in the absence of inventor knowledge of the best mode, where the corporate assignee knows of and affirmatively conceals that mode.

PARTIES TO THE PROCEEDING

The parties are identified in the caption to the case.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Petitioner, Novopharm Ltd. (hereinafter "Novopharm"), respectfully petitions for a writ of certiorari to review the decision of the United States Court of Appeals for the Federal Circuit, entered in the above-entitled proceedings on April 21, 1995.

OPINION BELOW

The opinion of the Court of Appeals for the Federal Circuit is reported at 52 F.3d 1043, 4 U.S.P.Q.2d 1565 and reproduced in the Appendix ("App.") at pp. 1a-30a. The opinion and order of the district court, entered September 17, 1993, is reproduced in the App. at pp. 31a-58a.

JURISDICTION

The judgment of the Court of Appeals for the Federal Circuit was entered on April 21, 1995. Novopharm filed a petition for rehearing with a suggestion for rehearing *en banc*, which was denied on June 21, 1995. App. at 59a-60a. This Court has jurisdiction to review the judgment of the Court of Appeals for the Federal Circuit pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS AND RULES INVOLVED

The requirement to disclose the best mode in a patent application arises from 35 U.S.C. § 112, which provides in relevant part:

> The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention.

STATEMENT OF THE CASE

This case is one of alleged patent infringement. Jurisdiction arose under 28 U.S.C. § 1338(a). Glaxo, Inc. and Glaxo Group Limited ("Glaxo") charged Novopharm with patent infringement under 35 U.S.C. § 271(e) based on Novopharm's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration. That ANDA sought permission to manufacture and sell ranitidine hydrochloride tablets, as a generic equivalent to Zantac, the world's largest selling prescription medication. Zantac is used in the treatment of ulcers.

Specifically, Glaxo charged Novopharm with infringement of U.S. Patent No. 4,521,431 ("the '431 patent"). This patent relates to a specific crystalline form of the ranitidine hydrochloride drug, referred to as "Form 2" ranitidine hydrochloride. Novopharm admitted infringement of the '431 patent, but alleged that the claims of that patent were invalid under 35 U.S.C. § 102 as being anticipated by an earlier Glaxo patent, U.S. Patent No. 4,128,658 ("the '658 patent").

On July 24, 1992, Novopharm filed a motion to compel production of numerous documents withheld by Glaxo pursuant to a claim of privilege. Approximately nine months later, on April 27, 1993, the district court granted, in large part, Novopharm's motion to compel. *Glaxo, Inc. v. Novopharm Ltd.*, 148 F.R.D. 535 (E.D.N.C. 1993). Finally, on June 2, 1993, a mere two months before trial was scheduled to commence, Glaxo produced the documents subject to the district court's April 27, 1993 order. These documents indicated that Glaxo had violated 35 U.S.C. § 112 in failing to disclose the best mode of formulating Form 2 ranitidine hydrochloride so that it can be used in pharmaceutical compounds – the only known use for ranitidine hydrochloride.

The best mode requirement of § 112 imposes an affirmative obligation on the patent applicant to disclose, in its patent application, the best mode known to it for practicing the claimed invention at the time the application is filed. The best mode requirement is part of the *quid pro quo* for obtaining the seventeen year monopoly provided by the government via the issuance of a patent. It ensures that the public, upon expiry of the patent, will be able to effectively practice the invention claimed in that patent.

Armed with this new evidence of a best mode violation by Glaxo, Novopharm, on June 21, 1993, filed a motion for summary judgment that the '431 patent was invalid because of Glaxo's failure to disclose the best mode known to it of carrying out the "invention" claimed therein. In the alternative, Novopharm asked to be given discovery on the issue. Glaxo defended on the basis that

knowledge of the withheld best mode must be the personal knowledge of the inventor and that undisputed knowledge of the withheld best mode by others within Glaxo, even those closely associated with obtaining the patent, could not, as a matter of law, establish a best mode violation. In further support of its opposition, Glaxo submitted a Declaration by the inventor, Dr. Crookes, in which he states, in ambiguous terms, that he had no knowledge of the withheld best mode. Novopharm's summary judgment motion was denied on August 4, 1993, five days before the scheduled commencement of the trial.

In the interim, however, at the pre-trial conference of July 28, 1993, the district court allowed the best mode defense to be tried as an issue in the case. The very next day, Novopharm sought to take discovery on that issue, including taking the deposition of the Glaxo inventor, Dr. Crookes, in an attempt to cross-examine the ambiguous statements made in his Declaration. Glaxo resisted the discovery, and sought a protective order from the district court. The district court thereafter denied Novopharm *any* discovery on the best mode issue (including taking the deposition of Dr. Crookes). The district court did order Glaxo to produce at trial as an adverse witness its in-house patent agent who was responsible for handling the patent application leading to the '431 patent.

The trial then commenced on August 9, 1993, and ended eight trial days later, on August 18, 1993. Although Dr. Crookes had been listed as a trial witness, Glaxo, in a most unusual move, never called Dr. Crookes and Novopharm was denied any opportunity to examine Dr. Crookes as to the best mode issue. On September 17,

1993, the district court issued an Order finding for Glaxo on all the issues in the case.

Specifically, on the best mode defense under § 112, the district court found (a) that everyone involved in the filing of both Glaxo's British and U.S. patent application on Form 2 was aware, prior to the filing date of either application, of Glaxo's best mode of formulating Form 2 ranitidine hydrochloride into pharmaceutical compositions, (b) that Glaxo *intentionally* did not disclose this mode in the '431 patent (and instead kept it as a Glaxo trade secret), and (c) that Glaxo's failure to disclose this best mode in the '431 patent applied to each claim of that patent. (App. at 54a-57a). Even though Glaxo could have called the named inventor, Dr. Crookes, to testify whether he knew about this best mode, Glaxo chose not to do so. Despite the absence of testimony by Dr. Crookes, and the unrefuted evidence that both his attorney and supervisor did know of the withheld best mode, the district court found that Novopharm had not proven Dr. Crookes personally knew of the best mode. The district court, on that basis alone, felt compelled by the decision in *Texas Instruments v. U.S.I.T.C.*, 871 F.2d 1054 (Fed. Cir. 1989), to find no best mode violation. (App. at 56a-57a).

Novopharm appealed, arguing that the district court improperly denied Novopharm discovery on the best mode issue, and improperly found that inventor Dr. Crookes did *not* know of the best mode. Novopharm also argued that even if Dr. Crookes did not know of the best mode, the fact that those within Glaxo responsible for the U.S. patent application knew, and intentionally concealed that mode, was sufficient to find a best mode violation

under precedent from the Federal Circuit and other courts interpreting § 112.

In April of 1994, Novopharm argued its case to the Federal Circuit. Shortly thereafter, one of the panel members involved in the appeal, Judge Clevenger, recused himself from the case, and was replaced by Judge Rich. During the pendency of Novopharm's appeal, on July 10, 1994, another panel of the Court of Appeals for the Federal Circuit heard oral argument in *CPC International v. Archer Daniels Midland*, Nos. 94-1045, -1060 (Fed. Cir. July 11, 1994). That case involved the identical best mode issue as that in the *Glaxo v. Novopharm* appeal, that is, whether a best mode violation can be found where the corporation to whom the patent is assigned, but not the actual named inventor, knows of and conceals the best mode. The district court in *CPC* had reached the opposite conclusion from the district court in *Glaxo v. Novopharm*, finding a best mode violation on those facts. *CPC International v. Archer Daniels Midland*, 831 F.Supp. 1091, 1108 (D.Del. 1993).

One day after oral argument in *CPC*, the Federal Circuit panel hearing that case issued an unpublished, *per curiam* opinion affirming the district court. By using the vehicle of an unpublished opinion, that panel, pursuant to Federal Circuit Rule 47.6, indicated that its decision that a corporate assignee could be held liable for a best mode violation absent inventor knowledge, added nothing new to established case precedent.

On April 21, 1995, the panel in this case rendered its opinion, affirming the district court by a margin of 2-1.

Judge Rich, writing for the majority, held that it is "undisputed" that Glaxo inventor Crookes did not know of the concealed best mode. This holding was based on the court's review of the Crookes Declaration, which was not admitted into evidence by the district court, and on which Novopharm was allowed no discovery. Then, even though the panel agreed with the district court that corporate assignee Glaxo knew of and concealed the best mode, the majority found no best mode violation because of its holding that Crookes did not know. Judge Mayer dissented.

The majority based its affirmance on the holding in *Texas Instruments* cited by the district court, even though the only panel member who sat on *Texas Instruments*, Judge Mayer, argued that the majority was misconstruing the holding in that case. Moreover, the panel majority never mentioned the previous holding in *CPC* by a different panel, even though the *CPC* panel, on similar facts, reached the exact opposite conclusion, and even though the holding in *CPC* was an expression of the previous precedent of the Federal Circuit on this issue.

REASONS FOR GRANTING THE PETITION

SUMMARY OF ARGUMENT

Novopharm's due process rights were violated twice – first by the district court, and then by the Court of Appeals for the Federal Circuit. In the district court, Novopharm was allowed no discovery whatsoever on the issue of best mode violation. Thus, Novopharm was not allowed any discovery on the issue of whether inventor

Crookes knew of the concealed best mode that apparently everyone else involved with the patent knew of, and then was found to have not proved its case, because Novopharm didn't show that Crookes knew.

In the Court of Appeals for the Federal Circuit, Novopharm's argument that the district court erred in refusing to allow Novopharm discovery fell upon deaf ears. And then the Federal Circuit committed a due process violation of its own making. In affirming the district court, the Federal Circuit found its own facts over and above those found by the district court. Specifically, the Federal Circuit found that inventor Crookes did not know of the concealed best mode, relying on the Crookes Declaration, even though Novopharm was allowed no discovery relating to the Declaration and even though the Declaration was not admitted into evidence at trial.

Moreover, in holding that inventor knowledge is necessary to find a best mode violation, the panel majority in *Novopharm* is at odds with another panel of that same Court. As stated above, in *CPC International*, another panel of the Federal Circuit reached exactly the opposite conclusion from that of the panel majority in this case. Since the *CPC International* decision was issued as a unpublished opinion, it could not have been creating new precedent on this issue. Thus, in the opinion of the court in *CPC International*, it was established case precedent in the Federal Circuit to the effect that inventor knowledge of the concealed best mode is not necessary to find a best mode violation, provided that corporate assignee knowledge is shown. The panel majority here, therefore, could not overrule this precedent. *UMC Electronics Co. v. U.S.*, 816 F.2d 647, 652 n.6 (Fed. Cir. 1987).

Finally, the fact that different panels of the Federal Circuit reached different conclusions on the identical legal issue in cases submitted and heard at approximately the same time shows that the Federal Circuit is divided on this issue. Since the Federal Circuit is the only appellate court hearing appeals in patent cases, the polar opposite decisions in the present case and *CPC International*, in similar fact scenarios, is equivalent to a disagreement between circuits, which should be resolved by this Court. Otherwise, the impression is created that submission of an appeal to the Federal Circuit can be characterized as "appellate roulette," where the outcome of the appeal is dependent not on the issues presented, but on the composition of the panel hearing the appeal.

ARGUMENT

A. Novopharm's Due Process Rights Were Violated

1. The District Court

At trial, Novopharm proved that Glaxo's in-house patent agent in charge of Glaxo's U.S. patent application knew of the intentionally concealed best mode, and that the inventor's *direct supervisor*, Mr. Collin, also knew. Novopharm also proved that this patent agent, Mr. Brereton, had no contact whatsoever with the inventor during the drafting of Glaxo's initial British application or its U.S. applications, and that it was Glaxo's corporate policy to bypass inventors entirely in the drafting of Glaxo patent applications.

This evidence, which was uncontroverted by Glaxo, should have raised the inference that the inventor, Dr. Crookes, also knew of the concealed best mode. *Madison v. Deseret Livestock Co.*, 574 F.2d 1027, 1036 (10th Cir. 1978). This inference was particularly appropriate, because the district court denied Novopharm any discovery on the best mode issue, and Glaxo, at trial, removed *its employee* Dr. Crookes from its trial witness list. Glaxo could have attempted to rebut this inference by having Dr. Crookes testify at trial, yet it chose not to do so. By refusing to call Dr. Crookes as a witness, Glaxo prevented Novopharm from obtaining any information from Crookes on the state of his knowledge of the concealed best mode, because Crookes resides in England. Glaxo's refusal to produce Crookes for trial, in and of itself, is evidence that Crookes' testimony would have been adverse to Glaxo, i.e., that he *did* know about Glaxo's best mode. *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1399-1400 (Fed. Cir. 1986); *Jones v. Otis Elevator Co.*, 861 F.2d 655, 658-59 (11th Cir. 1988).

The district court, however, found that Novopharm had not proven that Crookes knew of the concealed best mode. This finding by the district court was fundamentally unfair, because the district court denied Novopharm an opportunity to affirmatively prove that Crookes knew, when it denied Novopharm discovery on the issue.

2. The Federal Circuit

On appeal, Novopharm argued that even if the best mode requirement looks to the knowledge of the inventor alone, Novopharm should still prevail, because it had

raised an inference that Crookes knew of the best mode, which went unrebutted by Glaxo. Glaxo simply presented no evidence whatsoever at trial on this issue, making the district court's failure to find that Crookes knew of the best mode clearly erroneous.

Despite this evidence presented by Novopharm, the panel majority found no best mode violation, because it, on its own, found that Crookes did not know of the best mode. It stated:

> There is simply no evidence in the record before us, indeed, Novopharm points to none, that the inventor of the '431 patent knew of and concealed the [best mode] when his application was filed.

(App. at 16a).

The panel majority thus went even further than the district court. The district court merely found that Novopharm had not proved that Crookes knew. The panel majority, however, made its own affirmative finding that Crookes did not know. In making this statement, the panel majority improperly relied on the Crookes Declaration, despite the fact it was not admitted at trial. Novopharm had no opportunity at any time to test the veracity of that Declaration, because (1) Novopharm was given no discovery by the district court, and (2) Glaxo removed Crookes, a resident of England, from its trial witness list.

Despite the non-evidentiary status of the Declaration, the panel majority stated:

> Inventor Crookes, in a declaration in opposition to Novopharm's best mode summary judgment

> motion, stated 'I did not know of the [best mode], or of its benefits, prior to commencement of this litigation. I did not – indeed, could not – consider the azeotrope process a "best mode" of making ranitidine hydrochloride tablets at the time of filing any patent application.' Crookes further indicated that he worked in a different department than those who worked in the azeotroping process.
>
> * * *
>
> It is undisputed that Crookes invented a compound and was not involved in whatever processes were to be used to commercially produce it.

(App. at 16a-17a).

The panel majority's use of this Declaration as the reason for not inferring that Crookes knew of the best mode process is a clear error of law, for several reasons. First, the panel majority's use of the Declaration to go beyond the findings made by the district court on this issue, where the district court did not rely in any way on the Declaration, is impermissible appellate fact finding.

Second, the majority's use of the Crookes Declaration violates Novopharm's right to due process. Although Novopharm was not given any discovery of Dr. Crookes on this issue, Dr. Crookes never testified at trial, and his Declaration was never entered into evidence, the panel majority relied on that very same Declaration to affirm the district court. This action, Novopharm submits, rises to the level of a violation of Novopharm's constitutional right of due process, because Novopharm was denied its right of cross-examination as to the very evidence relied

upon by the panel majority to decide the best mode issue against Novopharm. *Greene v. McElroy*, 360 U.S. 474, 496-97, 3 L.Ed.2d 1377, 1391 (1959).

The panel majority's decision to credit an untested Declaration, never offered or received into evidence at trial, has ominous implications. If what the majority did here is legally correct, then why should a party ever have a witness testify at trial, subject to cross examination? It would be far safer to have the witness just submit a carefully crafted declaration, which the party could then rely upon at the appeal.

The panel majority strayed far from its proper appellate function in deciding the best mode issue against Novopharm. Novopharm raised the inference that Crookes knew of the concealed best mode, and that inference went unrebutted by Glaxo if, as is proper, the Declaration is not considered.

B. A Best Mode Violation Can Be Found In The Absence Of Inventor Knowledge

Review of the holding of the panel majority regarding the best mode issue in this case is necessary to resolve conflicting views of two panels of the Federal Circuit on the issue of whether the best mode requirement of § 112 can be violated by a corporate assignee in the absence of inventor knowledge. Here, the panel majority held that knowledge and concealment of the best mode by the corporate assignee, Glaxo, cannot, as a matter of law, violate the best mode requirement. However, in the previous unpublished *CPC International* opinion, three

judges of the Federal Circuit held exactly the opposite, on facts less egregious than those here.

In *CPC International v. Archer Daniels Midland*, 831 F.Supp. 1091, 30 U.S.P.Q.2d 1427 (D.Del. 1993), the district court held that the patent-in-suit was invalid, because the patent assignee failed to disclose the best mode known to it, even though it was undisputed that the inventor did *not* know of this mode. Relying on *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1209-1210, *cert. denied*, 116 L.Ed.2d 132 (1991) and *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987), the district court stated:

> Because CPC was primarily involved in the preparation and filing of the patent application, the purpose of the statute would not be served merely by looking to [the inventor's] intent at the time the application was filed. The Court must consider the information available to both [the inventor] and his agent, CPC, at the time they applied for the patent.

CPC International, 831 F.Supp. at 1108.

Applying the above analysis, the district court in *CPC International* found a best mode violation, and consequently held the patent invalid. This was the only ground of invalidity found by the district court.

On appeal, three judges of the Federal Circuit, Judge Nies, Judge Rader, and Senior Judge Cowen, affirmed that holding by the district court in an unpublished opinion. By using the vehicle of an unpublished opinion, that panel, pursuant to Rule 47.6, indicated that its decision that a corporate assignee could be held liable for a best

mode violation absent inventor knowledge, added nothing new to established case precedent.

If the *CPC International* panel's holding with respect to corporate assignee knowledge was not supported by case precedent, or was a holding for which there was no precedent, it could not have issued its opinion under Federal Circuit Rule 47.6. Thus, assuming that the *CPC International* panel was correct in its use of Rule 47.6, the majority's decision to the contrary on that issue in this case is legal error. It is black letter law that an appellate panel cannot itself overrule case precedent from its circuit. *UMC Electronics Co.*, 816 F.2d at 652 n.6. Yet, that is exactly what the majority did here.

Most importantly, the *CPC International* panel was right in its interpretation of § 112. Prior to the present case, both the case law and the intent of Congress in drafting § 112, support the proposition of assignee accountability on the issue of best mode. The applicable case law, which includes *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1209-1210, *cert. denied*, 116 L.Ed.2d 132 (1991); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931 (Fed. Cir.), *cert. denied*, 498 U.S. 920 (1990); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987); *Columbia Broadcast System v. Sylvania Electric Products*, 415 F.2d 719, 725 (1st Cir. 1969), *cert. denied*, 396 U.S. 1061 (1970); and *ITT v. Union Carbide Corp.*, 210 U.S.P.Q. 496, 501, 509, 513 (D.S.C. 1981), is, Novopharm submits, clear and unequivocal on this point.

In opposition, the panel majority here cited a single case: *Texas Instruments v. U.S.I.T.C.*, 871 F.2d 1054 (Fed. Cir. 1989), the same case advanced by Glaxo at trial and on appeal. The panel majority stated:

> As the trial court correctly noted, we held in *Texas Instruments* that there was no violation of the best mode requirement of § 112 by knowledge of the *purported* best mode on the part of T.I. employees, *other than the inventor*, in the manufacturing group when the inventor did not know of or conceal this best mode.

(App. at 15a-16a).

As Judge Mayer points out in his dissent, however, *Texas Instruments* does not limit the best mode inquiry to the inventor's actual knowledge. (App. at 25a-26a). Judge Mayer's view as to the import of *Texas Instruments* should be given substantial weight, since he, and not either member of the majority here, was on the panel that decided *Texas Instruments*. Further, if *Texas Instruments* had the import attributed to it by the majority, the *CPC International* panel could never have decided its appeal in the way it did. Thus, the three judges on that panel also disagree with the conclusions drawn by the majority regarding the holding with respect to best mode in the *Texas Instruments* case.

The panel majority's opinion, as the dissent recognizes, is a "pinched reading of the best mode requirement" that "violates at least the spirit of the [requirement] at the public's expense." (App. at 29a). Ignoring the knowledge of the corporate assignee fosters a "head in the sand" mentality for corporate applicants, and allows corporate applicants to obtain patents without

giving the public the *quid pro quo* best mode information. *See Amgen*, 927 F.2d at 1209-1210 ("The best mode requirement is intended to insure that a patent applicant plays 'fair and square' with the patent system.") The majority's opinion, as the dissent states, "is a perverse interpretation of the law." (App. at 22a). It is at odds with established case law, the unpublished opinion of a panel of this court in *CPC*, and with the intent behind § 112, as expressed in *Amgen*.

Novopharm's petition should be granted, and the panel majority reversed. This conflict between judges of the Federal Circuit, the only appellate court to which patent appeals can be taken, must be resolved. The situation is essentially the same as that existing where two Circuit Courts of Appeal are in conflict with respect to an issue of law. Those situations historically have been resolved by this Court, because to allow such a situation to persist frustrates our system of justice in that the outcome of a given case can hinge on the place in which the litigation is brought, rather than on the merits of the case itself.

That is what has happened here. Novopharm has been subjected to a game of "appellate roulette" and has come up a loser. If it had drawn the *CPC International* panel, it would have won its appeal. However, merely because Novopharm drew a different panel, and for no other reason, it lost.

CONCLUSION

For all the foregoing reasons, Novopharm respectfully requests that the Court issue a writ of certiorari to review the judgment of the Court of Appeals for the Federal Circuit.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

94-1026

GLAXO INC. and GLAXO GROUP LIMITED,

Plaintiffs-Appellees,

v.

NOVOPHARM LTD.,

Defendant-Appellant.

Stephen B. Judlowe, Hopgood, Calimafde, Kalil, Blaustein & Judlowe, of New York, New York, argued for plaintiffs-appellees. With him on the brief were *William G. Todd* and *Janet B. Linn*. Also on the brief were *Steven P. Lockman*, Arnold & Porter, of Washington, D.C. and *Joseph W. Eason*, Moore & Van Allen, of Raleigh, North Carolina, of counsel.

Robert F. Green, Leydig, Voit & Mayer, LTD., of Chicago, Illinois, argued for defendant-appellant. With him on the brief were *John E. Rosenquist* and *Jeffrey S. Ward*.

Appeal from: U.S. District Court for the Eastern District of North Carolina

Judge Boyle

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

94-1026

GLAXO INC. and GLAXO GROUP LIMITED,

Plaintiffs-Appellees,

v.

NOVOPHARM LTD.,

Defendant-Appellant.

DECIDED: April 21, 1995

Before ARCHER, *Chief Judge*, RICH, and MAYER, *Circuit Judges*.

Opinion for the court filed by Circuit Judge RICH. Dissenting opinion filed by Circuit Judge MAYER.

RICH, *Circuit Judge*.

Novopharm Ltd. (Novopharm) appeals the judgment of the United States District Court for the Eastern District of North Carolina, *Glaxo, Inc. v. Novopharm Ltd.*, 830 F. Supp. 871, 29 USPQ2d 1126 (E.D.N.C. 1993), that United States Patent No. 4,521,431 was not invalid and was infringed, and enjoining Novopharm from the commercial manufacture or sale of the patented crystalline form of ranitidine hydrochloride. We affirm.

Background

Glaxo Inc. and Glaxo Group Ltd. (collectively Glaxo) are the owner and exclusive United States licensee, respectively, of United States Patent No. 4,521,431 ('431

patent). The '431 patent claims a specific crystalline form of the compound ranitidine hydrochloride, designated as "Form 2," which Glaxo markets as an antiulcer medication under the brand name Zantac.[1] The '431 patent issued on June 4, 1985.

In 1976, Glaxo chemists investigating potential anticulcer medications synthesized an aminoalkyl furan derivative, later named ranitidine, which proved to be a potent histamine blocker, inhibiting the secretion of stomach acid. Later that year, Glaxo filed an application for a patent on ranititdine in the United Kingdom. It followed with an application for a United States patent, which issued as No. 4,128,658 ('658 patent) on December 5, 1978. The '658 patent claims a number of structurally similar compounds, including ranitidine and its hydrochloride salt. It discloses one method for preparing ranitidine hydrochloride, set forth in the '658 patent as Example 32.[2]

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[1] Claims 1 and 2 of the '431 patent, in issue here, read:

> 1. Form 2 ranitidine hydrochloride characterised by an infra-red spectrum as a mull in mineral oil showing the following main peaks: [list of peaks]
>
> 2. Form 2 ranitidine hydrochloride according to claim 1 further characterised by the following x-ray powder diffraction pattern expressed in terms of "d" spacings and relative intensities (1) (s=strong, m=medium, w=weak, v=very, d=diffuse) and obtained by the Debye Scherrer method in a 114.6 mm diameter camera by exposure for 12 hours to CoK radiation and for 3 hours to CuK radiation: [table]

The '431 patent also claims various pharmaceutical compositions and methods of using Form 2 ranitidine hydrochloride. These claims are not at issue in this case.

[2] Developed by Glaxo's David Collin in June 1977, that method involves dissolving ranitidine in industrial methylated

Glaxo prepared large quantities of ranitidine hydrochloride between 1977 and 1980 for use in toxicology and clinical studies. Instead of using the process of Example 32, however, Glaxo's chemists prepared this material using a similar process that they labelled Process 3A. They later developed a more efficient method that they called Process 3B. Until April 15, 1980, both Process 3A and Process 3B yielded ranititdine hydrochloride identical in all respects to that originally produced using the Example 32 procedure.

On that date, however, Glaxo's Derek Crookes used Process 3B to prepare crystalline ranitidine hydrochloride that was visibly different from all previous batches of the salt. The difference was confirmed by infra-red (IR) spectroscopy and x-ray powder diffraction, which revealed that the new product was a crystalline form, or polymorph, of ranitidine hydrochloride that differed from the previously known form. Glaxo began to refer to this new polymorph as Form 2 ranitidine hydrochloride (designating the old polymorph as Form 1).

Because Form 2 had better filtration and drying properties, making it better suited for commercial applications, Glaxo decided to proceed with commercialization of Form 2 rather than Form 1. Form 2 was hampered by poor flow properties, however, which made the material difficult to measure and dispense in its pure form.

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spirit containing dissolved hydrogen chloride gas. Ethyl acetate is added to the solution, and ranitidine hydrochloride precipitates from solution as a crystalline solid characterized by a melting point of 133-134°C.

Accordingly, Glaxo scientists developed a novel azeotroping process[3] to granulate the Form 2 salt, which made it much easier to make into pharmaceutical compositions. This process was the subject of a British patent application that Glaxo eventually abandoned without disclosing the process to the public.

Glaxo filed a patent application covering Form 2 ranitidine hydrochloride in the United Kingdom on October 1, 1980. It filed a United States application thereon the next year, which eventually issued as the '431 patent in suit. When George Graham Brereton, Glaxo's patent officer initially charged with pursuing the United States application, learned of the azeotrophic granulation process and Glaxo's desire to keep that process secret, he recommended that Glaxo not claim pharmaceutical compositions of the Form 2 salt for fear of violating the best mode requirement. Brereton apparently believed that disclosure of the azeotroping process would be necessary because it was the best way to make the Form 2 salt for use in preparing pharmaceutical compositions. He later

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[3] Azeotroping is a technique for separating a chemical mixture, the components of which would otherwise be difficult to separate because of the similarity of their boiling points. An additional substance is added to the mixture, selected for its ability to interact with a component of the original mixture to form an azeotrope – a mixture of substances "the composition of which does not change upon distillation." *See McGraw-Hill Dictionary of Scientific and Technical Terms* 162 (4th ed. 1989). If the proper substance is selected, the resulting azeotrope will have a boiling point that differs substantially from the desired component of the original mixture. The desired component can then be successfully separated from the azeotrope by distillation. *See Hawley's Condensed Chemical Dictionary* 109 (11th ed. 1987).

moved to another position at Glaxo. The U.S. application was eventually amended to include pharmaceutical composition claims, but Glaxo did not amend the specification to disclose the azeotroping process.

On August 9, 1991, Novopharm Ltd. filed an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA), seeking FBA approval to manufacture and sell a generic version of Form 2 ranitidine hydrochloride beginning December 5, 1995, the expiration date of the '658 patent, well before the expiration date of the '431 patent in 2002. Glaxo filed this suit for patent infringement on November 13, 1991, alleging technical infringement of claims 1 and 2 of the '431 patent by the ANDA filing as provided in 35 U.S.C. § 271(e)(2) (1988). Novopharm admitted infringement of the claims, but contended that the '431 patent was invalid because it was anticipated by the disclosure of the '658 patent.

Novopharm later amended its answer to add the defense of inequitable conduct arising from alleged false and misleading affidavits provided to the U.S. Patent and Trademark Office (PTO) during prosecution of the applications from which the '431 patent issued. Finally, on June 21, 1993, Novopharm sought summary judgment based on a third defense, Glaxo's alleged failure to disclose the best mode of practicing the claimed invention. The trial court denied the motion, and the case was tried to the court beginning on August 9, 1993.

On the question of anticipation, the court found that Novopharm had not carried its burden of proving by clear and convincing evidence that practice of Example 32 of the '658 patent always produced Form 2 ranitidine

hydrochloride, so that Form 2 was not inherently disclosed by Example 32. As for inequitable conduct, the court agreed with Novopharm that the affidavits presented to the examiner were misleading and material, but it found that Novopharm had failed to prove any deceptive intent. The court also concluded that there was no violation of the best mode requirement because Novopharm had not proved that Crookes, the inventor, knew of the best mode, the statute and this court's precedent providing that knowledge by the inventor himself is required. Accordingly, the court held that the '431 patent was not invalid, was enforceable and infringed, and ordered that Novopharm refrain from commercial manufacture or sale of Form 2 ranitidine hydrochloride before the '431 patent expires. Novopharm appeals.

Discussion

I. Example 32, Anticipation

We consider first Novopharm's argument that the district court erred in holding that Novopharm did not prove that the claims in suit of the '431 patent were anticipated by Example 32 of the '658 patent. Anticipation is a factual matter, which we review under the clearly erroneous standard. *Diversitech Corp. v. Century Steps Inc.*, 850 F.2d 675, 677, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988). A claim is anticipated and therefore invalid only when a single prior art reference discloses each and every limitation of the claim. 35 U.S.C. § 102(a) (1988); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1571, 230 USPQ 81, 84 (Fed. Cir. 1986). The disclosure need not be express, but may anticipate by inherency where it would be appreciated by one of ordinary skill in the art. *Continental*

Can Co. USA Inc. v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

Novopharm maintains that the invention claimed in the '431 patent, ranitidine hydrochloride in its Form 2 crystalline polymorph, is inherently disclosed in the '658 patent because the practice of Example 32 always yields ranitidine hydrochloride in its Form 2 polymorph. Novopharm's experts performed the process disclosed in Example 32 of the '658 patent thirteen times and each time they made Form 2 crystals, not Form 1 as Glaxo claims.

But the district court found that the practice of Example 32 could yield crystals of either polymorph. It specifically found that Glaxo's David Collin originally made Form 1 by practicing Example 32, and that Glaxo's expert, Nicholas Crouch, did too.[4] We are not persuaded that these findings are clearly erroneous. The district court correctly rejected the anticipation defense.

II. Inequitable Conduct

Novopharm contends the the trial court erred as a matter of law in declining to infer an intent to deceive from Glaxo's material misrepresentations to the PTO. The charge of inequitable conduct arises from a declaration

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[4] Novopharm suggests that the court was wrong in finding that these experiments were within the scope of Example 32 because they employed procedures that sometimes departed from the strict letter of Example 32. The district court found that one skilled in the art would understand that these procedures were consistent with the teaching of Example 32. We do not see where the court erred in this finding.

submitted by John Harold Hunt, the head of Glaxo's spectroscopy group, in response to a rejection in light of the product of Example 32 of the '658 patent.[5]

To prevail on its inequitable conduct defense, Novopharm had to show by clear and convincing evidence that Glaxo misrepresented facts to the PTO during prosecution of the '431 patent, that the misrepresentation was material, and that Glaxo acted with the intent to deceive the PTO. *Kingsdown Medical Consultants Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872, 9 USPQ2d 1384, 1389 (Fed. Cir. 1988). We review the district court's ultimate determination for abuse of discretion; the subsidiary factual questions of whether there was a misrepresentation, its materiality, and intent to deceive are reviewed for clear error. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1215, 18 USPQ2d 1016, 1028 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991).

On August 28, 1983, the examiner rejected claims 1 and 2 of Glaxo's Form 2 ranitidine hydrochloride patent application as anticipated by or obvious in light of the disclosure of the '658 patent. Glaxo argued that its claims were drawn to a specific crystalline form of ranitidine hydrochloride different from the compound disclosed in the '658 patent. The examiner asked for a showing that the claimed Form 2 ranitidine hydrochloride was patentably distinct from the prior art composition.

To overcome the rejection, Glaxo submitted Hunt's declaration comparing the IR spectra and x-ray powder

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[5] The case was complicated by the trial court's inability to hear testimony from Hunt due to his death in 1985.

diffraction patterns of the two crystalline forms. The declaration concluded that there were significant differences between the two products; a second declaration attested to the practical differences between the two polymorphs that made the Form 2 ranitidine hydrochloride preferable for commercialization.

Intent is often inferred from surrounding circumstances when a material misrepresentation is shown. *Paracon Podiatry Lab. v. KLM Lab.*, 984 F.2d 1182, 1189, 25 USPQ2d 1561, 1567 (Fed. Cir. 1993). But an inference is not required in every case, even when the misrepresentation is in affidavit form. Glaxo admits that the Form 1 data submitted with the Hunt declaration was not obtained from ranitidine hydrochloride prepared according to Example 32 of the '658 patent. The trial court concluded from this that the declaration was misleading, because it suggested falsely that the data had been obtained from the product of Example 32. The court also found that the misstatement was material. But it nevertheless concluded that an inference of fraudulent intent was unwarranted. We have not been persuaded otherwise.

The court found that as head of spectroscopy, Hunt was familiar with data obtained from Form 1 material, including that originally made by Collin according to Example 32. He knew that in each case the Form 1 data was different from that obtained for Form 2. The court found that there was no difference between the IR spectrum of the Form 1 hydrochloride obtained according to Example 32 and that obtained by other methods. Likewise, although the Example 32 material was never subjected to x-ray diffraction analysis, material produced by

other methods yielded a consistent powder diffraction pattern that was different from that obtained from Form 2 crystals; this material exhibited an IR spectrum identical to that of the Example 32 material.

The trial court concluded that Hunt did not believe there were any differences between material produced using Example 32 and the material from which he obtained the data analyzed in his declaration. Accordingly, the court found that Novopharm failed to carry its burden of proving intent to deceive by clear and convincing evidence. Although this conclusion is debatable, that is not sufficient reason to reverse in the absence of firm and definite belief that the district court erred.

III. Best Mode

Novopharm next asserts that Glaxo failed to disclose the best mode of practicing the invention, that is, the azeotroping process it uses to formulate the claimed Form 2 ranitidine hydrochloride into pharmaceutical compositions. The best mode defense arose little more than two months before trial just after Glaxo produced documents based on which Novopharm filed a motion for summary judgment of invalidity for failure to disclose the best mode. Less than a week before trial, the district court denied Novopharm's motion stating that "the court cannot hold as a matter of law that Dr. Crookes knew that the azeotroping process was the best mode of manufacturing ranitidine hydrochloride, and summary judgment must therefore be denied." *Glaxo, Inc. v. Novopharm Ltd.*, 830 F.Supp. 869, 871 (E.D.N.C. 1993). The district court further stated that it reserved for trial "ruling on the

question of whether and to what extent the knowledge of other Glaxo employees and agents may be imputed to Dr. Crookes for purposes of finding a best mode analysis [sic, violation]." *Id.*

At trial, Novopharm produced evidence that officials at Glaxo knew of the azeotroping process and considered it to be the best mode of making Form 2 ranitidine hydrochloride into a pharmaceutical composition. Novopharm argued in district court, as it does here, that the knowledge of the azeotroping process by Glaxo officials should be imputed to inventor Crookes for purposes of finding a best mode violation.

The trial court found Novopharm's argument to have some "intuitive appeal" since Glaxo "has enjoyed the monopoly the issued patent provides." *Glaxo*, 830 F.Supp. 871, 881-82, 29 USPQ2d 1126, 1134 (E.D.N.C. 1993). Indeed, the trial court stated that if it were to impute the knowledge of others to the inventor of the '431 patent, "then clearly the court would be required to find a best mode violation." *Id.* at 882. The trial court concluded, however, that the statute, 35 U.S.C. § 112, first paragraph, and this court's holding in *Texas Instruments, Inc. v. United States International Trade Commission*, 871 F.2d 1054, 10 USPQ2d 1257 (Fed. Cir. 1989) do not permit using imputed knowledge in a best mode analysis. The district court concluded that Novopharm "as a matter of law- . . . failed to show the '431 patent should be invalidated based on a best mode violation." *Id.* at 882. On appeal, Novopharm asserts that the district court erred as a matter of law in holding that a best mode defense cannot be found in the absence of proof that the inventor knew of that mode.

The statutory provision at issue sets forth that:

> The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, first paragraph (1988).

The statutory language could not be clearer. The best mode of carrying out an invention, indeed if there is one, to be disclosed is that "contemplated by the inventor." That the best mode "belongs" to the inventor finds consistent support in previous statutory language as well.[6] Additionally, the commentary on the 1952 Patent Act states with respect to the best mode provision that "[t]his requirement, it should be noted, is not absolute, since it only requires disclosure of the best mode contemplated by the inventor, presumably at the time of filing the application." P.J. Federico, Commentary on the New Patent Act, 35 U.S.C.A. 1, 25 (1954).

In arguing that Glaxo did not comply with the best mode requirement of § 112, first paragraph, Novopharm

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[6] The 1793 Act stated: "in the case of any machine [the inventor] shall fully explain the principle, and the several modes in which he has contemplated the application of that principle or character, by which it may be distinguished from other inventions." Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318.

The 1836 Act stated: "in case of any machine, [the inventor] shall fully explain the principle, and the several modes in which he has contemplated the application of the principle or character by which it may be distinguished from other inventions." Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117.

The Act of 1870 changed the 'several modes' provision of the previous Acts to the present-day 'best mode.' Act of July 8, 1870, ch. 230, § 26, 16 Stat. 198.

relies on *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991), for the proposition that the best mode requirement lies at the heart of the statutory quid pro quo of the patent system. This is true enough. However, *Amgen*, consistent with the statute, speaks of the best mode requirement in terms of the best mode contemplated by the inventor. *Amgen*, 927 F.2d at 1210, 18 USPQ2d at 1024 ("Our case law has interpreted the best mode requirement to mean that there must be no concealment of a mode known *by the inventor* to be better than that which is disclosed.") (emphasis added). In fact, as we have previously stated, the sole purpose of the best mode requirement "is to restrain *inventors* from applying for patents while at the same time concealing from the public preferred embodiments of *their inventions* which *they* have in fact conceived." *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 926, 16 USPQ2d 1033, 1035 (Fed. Cir. 1990) (emphasis added) (*quoting In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA 1962)); *see Dana Corp. v. IPC Ltd. Partnership*, 860 F.2d 415, 419, 8 USPQ2d 1692, 1696 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989).

The best mode inquiry focuses on the inventor's state of mind at the time he filed his application, raising a subjective factual question. *Chemcast*, 913 F.2d at 926, 16 USPQ2d at 1035. The specificity of disclosure required to comply with the best mode requirement must be determined by the knowledge of facts within the possession of the inventor at the time of filing the application. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535, 3 USPQ2d 1737, 1745 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987).

That the best mode inquiry is grounded in knowledge of the inventor is even more evident upon contrasting the best mode requirement of § 112 with the enablement requirement of that section. *Chemcast,* 913 F.2d at 926, 16 USPQ2d at 1035. "Enablement looks to placing the subject matter of the claims generally in the possession of the public." *Spectra-Physics,* 827 F.2d at 1532, 3 USPQ2d 1742. Best mode looks to whether specific instrumentalities and techniques have been developed by the inventor and known to him at the time of filing as the best way of carrying out the invention. *Id.; Chemcast,* 913 F.2d at 927-28, 16 USPQ2d at 1036. The enablement requirement, thus, looks to the objective knowledge of one of ordinary skill in the art, while the best mode inquiry is a subjective, factual one, looking to the state of mind of the inventor. Indeed, recently this court in addressing whether an applicant's best mode had to be updated upon filing a continuation application affirmed that the best mode requirement "focuses on what the *inventor* knows." *Transco Prods. Inc. v. Performance Contracting, Inc.,* 38 F.3d 551, 558, 32 USPQ2d 1077, 1083 (Fed. Cir. 1994) (emphasis added), *cert. denied,* 130 L.2d 1069 (1995).

Based on the clear wording of the statute and our case law, the trial court properly rejected Novopharm's "imputed knowledge" best mode defense. As the trial court correctly noted, we held in *Texas Instruments* that there was no violation of the best mode requirement of § 112 by reason of knowledge of the *purported* best mode on the part of T.I. employees, *other than the inventor,* in the manufacturing group when the inventor did not know of

or conceal this best mode. *Texas Instruments*, 871 F.2d at 1061, 10 USPQ2d at 1262.

There is simply no evidence in the record before us, indeed Novopharm points to none, that the inventor of the '431 patent knew of and concealed the azeotroping process when his application was filed. Inventor Crookes in a declaration in opposition to Novopharm's best mode summary judgment motion stated "I did not know of any azeotroping of ranitidine hydrochloride, or of its benefits, prior to commencement of this litigation. I did not – indeed, could not – consider the azeotrope process a 'best mode' of making ranitidine hydrochloride tablets at the time of filing any patent application." Crookes indicated that he worked in a different department than those who developed the azeotroping process.

As the district court observed, the record does indicate, however, that others at Glaxo knew of the azeotroping process and knew that this process would be used commercially to produce pharmaceutical forms of the claimed product.[7] The record also indicates that these individuals as well as their English patent agent were concerned that failure to disclose the azeotroping process may present a best mode problem. However, in neither instance did Glaxo nor its patent agent appropriately consider that inventor Crookes knew nothing of the

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[7] The claims at issue are not directed to a pharmaceutical compound. Therefore, there may be a question whether the azeotroping process is indeed the best mode of carrying out the *claimed* invention. *See Chemcast*, 913 F.2d at 927, 16 USPQ2d at 1036. In view of our decision, however, it is not necessary for us to reach this issue.

azeotroping process. That Glaxo thought it may have a best mode problem either because of its incorrect or incomplete consideration of U.S. patent law does not make it so.

Novopharm maintains that Glaxo intentionally isolated Crookes from knowledge of the azeotroping process leaving "it to others to commercialize and reduce the invention to practice." Thus, Novopharm fears that Glaxo purposefully prevented the inventor from gaining knowledge of the most advantageous application for his invention, the azeotroping process, so that that process could be maintained as a trade secret. That fear does not equate with a best mode violation.

In this case, Crookes was unconcerned with the commercialization of the claimed compound. It is undisputed that Crookes invented a compound and was not involved in whatever processes were to be used to commercially produce it. Therefore, whether Glaxo deliberately walled off the inventor is irrelevant to the issue of failure of his application to disclose the best mode known to him.

In arguing that Crookes was screened from knowledge, Novopharm relies on testimony of Glaxo's in-house patent agent that Crookes was not consulted "at any time" during the preparation of the application that matured into the '431 patent. This however, completely ignores the requirement that patents are applied for "in the name of the actual inventor or inventors" according to 37 C.F.R. § 1.41(a) (1983). The inventor(s) must submit an oath or declaration attesting that they have "reviewed and understand[ ] the contents of the specification" and

believe "the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought." 37 C.F.R. § 1.63(b)(1), (2) (1992); see also 37 C.F.R. § 1.51(a)(2) (1992). Moreover, this court in *Sun Studs, Inc. v. Applied Theory Associates, Inc.*, 772 F.2d 1557, 1568, 227 USPQ 81, 89 (Fed. Cir. 1985), recognized that 35 U.S.C. § 111 (1988) "requires that the *inventor* must apply for the patent." *Sun Studs*, 772 F.2d at 1568, 227 USPQ at 89 (emphasis in original). Novopharm has not alleged that these requirements were violated.

It is therefore presumed that Crookes, the inventor and applicant, must have reviewed the specification and signed the required declaration before the application was filed. Without more, Novopharm is simply wrong when it alleges that Crookes had nothing to do with determining what needed to be disclosed in his patent application.

Novopharm additionally contends that looking solely to the inventor's knowledge in a best mode analysis "makes a mockery of the best mode requirement, and fosters a 'head in the sand' mentality for corporate applicants."

However, the practical reality is that inventors in most every corporate scenario cannot know all of the technology in which their employers are engaged. Therefore, whether intentionally or not, inventors will be effectively isolated from research no matter how relevant it is to the field in which they are working. Separating scenarios in which employers unintentionally isolate inventors from relevant research from instances in which

employers deliberately set out to screen inventors from research, and finding a best mode violation in the latter case, would ignore the very words of § 112, first paragraph, and the case law as it has developed, which consistently has analyzed the best mode requirement in terms of knowledge of and concealment by the inventor. Congress was aware of the differences between inventors and assignees, *see* 35 U.S.C. §§ 100(d) and 152, and it specifically limited the best mode required to that contemplated by the inventor. We have no authority to extend the requirement beyond the limits set by Congress.

The dissent argues that imputing knowledge of others than the inventor to the inventor for purposes of considering what was "contemplated by the inventor" in a best mode analysis "may be necessary under appropriate circumstances, to protect the public's 'paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct.' " The dissent contends that such knowledge can be imputed to the inventor under principles of agency law stating that, "[a]n agent's acts and knowledge can be imputed to the principal when necessary to protect the interests of others, so long as the acts or knowledge in question fall within the scope of the agent's authority," citing Restatement (Second) of Agency, § 261.

The Restatement defines agency as "the fiduciary relation which results from the manifestation of consent by one person to another that the other shall act on his behalf and subject to his control, and consent, by the other so to act." Restatement (Second) of Agency, § 1.

The flaw in the dissent's analysis is that a patent attorney[8] does not enter into an agency relationship with the inventor for purposes of what is disclosed in the inventor's patent application. Simply, the inventor never authorizes his patent attorney to "act on his behalf" with respect to disclosing the invention. Or, in the terms used by the dissent, the scope of the patent attorney's authority does not include inventing, i.e., either supplementing or supplanting the inventor's knowledge of his own invention. Rather, the information disclosed in the inventor's patent application must be that which is actually known to him. The statute requires that he submit an oath to this effect. *See* 35 U.S.C. § 115 (1988).

An agency relationship may exist during prosecution before the PTO where the patent attorney is acting on the inventor's behalf. *See* 37 C.F.R. 1.56(a) (1992). An agency relationship does not exist, however, with respect to what an inventor must disclose in order to obtain a patent on his invention, which includes, of course, any best mode under § 112. Therefore, in addition to being inconsistent with § 112, as explained above, because an agency relationship does not exist for purposes of what is disclosed in a patent application, it would be improper to impute a patent attorney's knowledge of a best mode to the inventor for purposes of finding a best mode violation.

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[8] A "patent agent" is subsumed within this term as a patent agent acts as the inventor's attorney before the PTO. The label "patent agent" does not mean there is an agency relationship, rather than an attorney-client relationship, between the inventor and such individual for all purposes.

In any case, the dissent's application of general agency principles to the analysis of best mode disclosure under § 112 is an entirely new idea and is not existing law.

The trial court here correctly noted that this court has "found that the absence of a showing of actual knowledge by the inventor was dispositive of the defendant's best mode argument" and held that the law "does not permit using *imputed knowledge*" in a best mode defense. *Glaxo*, 830 F. Supp. at 881-82, 29 USPQ2d at 1135 (emphasis added). The district court therefore correctly rejected the best mode defense.

IV. Conclusion

Accordingly, the judgment of the United States District Court for the Eastern District of North Carolina is affirmed.

AFFIRMED

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

94-1026

GLAXO INC. and GLAXO GROUP LIMITED,

Plaintiffs-Appellees,

v.

NOVOPHARM LTD.,

Defendant-Appellant.

MAYER, *Circuit Judge*, dissenting.

With this case, the court blesses corporate shell games resulting from organizational gerrymandering and willful ignorance by which one can secure the monopoly of a patent while hiding the best mode of practicing the invention the law expects to be made public in return for its protection. Because I believe this is a perverse interpretation of the law, I dissent.

The best mode requirement arises from the first paragraph of 35 U.S.C. § 112 (1988), which provides that the patent specification "shall set forth the best mode contemplated by the inventor of carrying out his invention." The best mode inquiry is twofold: first, did the inventor know of a preferred mode or embodiment of the invention; and second, did the inventor disclose that mode sufficiently to allow those skilled in the art to practice it. *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 928, 16 USPQ2d 1033, 1036 (Fed. Cir. 1990). The first question is largely subjective, looking to the inventor's knowledge and belief. The second is more objective, focusing on the

scope of the invention and the level of skill in the art. *Id.* Compliance with the best mode requirement is a factual question, which we review for clear error. *Engel Indus. Inc. v. Lockformer Co.*, 946 F.2d 1528, 1531, 20 USPQ2d 1300, 1302 (Fed. Cir. 1991). But this assumes a correct understanding of the relevant law, which we review de novo. *See Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1536, 3 USPQ2d 1737, 1745 (Fed. Cir. 1987).

Novopharm says Glaxo did not disclose the best mode of practicing the invention – the azeotropic granulation process it used to formulate ranitidine hydrochloride into pharmaceutical compositions. This defense became relevant only late in the game when, on June 2, 1993, Glaxo produced some documents that indicated that it had withheld information about the granulation process. Novopharm moved for summary judgment based on the best mode violation, which the district court denied, *Glaxo, Inc. v. Novopharm Ltd.*, 830 F. Supp. 869 (E.D.N.C. 1993), but allowed Novopharm to present the best mode defense at trial. Novopharm tried to take discovery on the issue, including a deposition of Crookes, the named inventor of the '431 patent, and Collin, his immediate supervisor. After Glaxo resisted and sought a protective order, the district court denied Novopharm any discovery, and the case proceeded to trial on August 9, 1993. At the close of Novopharm's case-in-chief on its best mode defense, the court decided to rule on that question as a mater of law, no factual issues remaining. Glaxo presented no evidence on the issue. The court held that because Crookes had no personal knowledge of the best mode, there was no requirement that it be disclosed.

Glaxo first suggests that the azeotropic granulation process was not an appropriate candidate for disclosure because it fell outside the scope of the claimed invention. Rather, Glaxo says the process is simply a production technique useful in the formulation of ranitidine hydrochloride into pharmaceutical compositions. It says the process is therefore relevant, if at all, only to the claims of the '431 patent that cover such compositions. No such claims are at issue here, so Glaxo says the best mode should not be considered.

But the statutory language demands that the patent disclose the best mode of "carrying out" the claimed invention. As the district court recognized, this language encompasses not only modes of making the invention, but of using it as well. *See Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 1563, 3 USPQ2d 1241, 1255 (Fed. Cir. 1987), *vacated on other grounds*, 486 U.S. 800 (1988). The azeotroping process was the best way to formulate raw ranitidine hydrochloride into pharmaceutical compositions suitable for use as a drug in human patients, the only use Glaxo contemplated for the invention. Glaxo admits the process was not generally known to those skilled in the art. Accordingly, the court could have found that disclosure of the process was required by section 112, so long as the other, subjective, elements of the best mode test were met. *Cf. Chemcast*, 913 F.2d at 930, 16 USPQ2d at 1038 ("Whether characterizable as 'manufacturing data,' 'customer requirements,' or even 'trade secrets,' information necessary to practice the best mode simply must be disclosed.").

The best mode inquiry begins with what the inventor knew when he filed his application. This subjective part

of the inquiry traditionally rests on the factual question whether the inventor actually contemplated a preferred mode: *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1036. But the inquiry is not limited to the inventor's actual knowledge.

The court believes *Texas Instruments, Inc. v. United States International Trade Commission*, 871 F.2d 1054, 10 USPQ2d 1257 (Fed. Cir. 1989), expressly limited best mode to the inventor's actual knowledge, but that case includes no such limitation. We merely agreed with the Commission that Texas Instrument's computer component patents were not invalid for failure to disclose the alleged best mode, a so-called "word boost" feature, because " '[t]he record does not disclose that the applicant knew of or concealed a better mode than he disclosed.' " 871 F.2d at 1061, 10 USPQ2d at 1262 (quoting Commission findings).

The problem arises from reading one sentence of the *Texas Instruments* opinion out of context. We said that "[t]he fact that Texas Instruments may have manufactured a DRAM containing a different or better form of boosting means is not pertinent to whether the specification disclosed" the best mode known to the inventors. *Id.* The court reads this to parallel the facts of our case – that the employer of the named inventors developed the alleged best mode wholly without the inventors' knowledge, and that there was no best mode problem because the inventors did not know of it.

But as our opinion in *Texas Instruments* shows, the inventors did know of the word boost feature, but did not believe that it was part of the best mode. *Id.* ("[T]hat the

inventors themselves did not consider the 'word boost' feature to be part of the best mode of their invention refutes any argument that the inventor 'knew of and concealed a better mode than he disclosed.' "). Accordingly, *Texas Instruments* stands only for the unremarkable proposition that there is no best mode violation where the inventor knew of the alleged mode and did not consider it to be a part of the preferred embodiment. It says nothing about whether specific knowledge of a best mode by a corporate assignee/employer may be imputed to the inventor/employee. Nor does any other precedent of this court.

As the district court recognized, "Glaxo, and not Crookes individually, . . . both directed the patent prosecution and has enjoyed the monopoly the issued patent provides." 830 F. Supp. at 881-82. Glaxo employees acted as agents for inventor Crookes during prosecution of the U.S. application. They were also agents for Glaxo, the assignee of the application and later the owner of the '431 patent. And that is the crucial point: Glaxo, not Crookes, brought this suit against Novopharm for infringement of the patent. Accordingly, Glaxo's conduct and knowledge during prosecution is important to the resolution of this case; it is not irrelevant, as the court says.

Glaxo says, and the court agrees, that it does not have to disclose the azeotroping process because Crookes did not know of that method of preparing pharmaceutical compositions of Form 2 ranitidine hydrochloride. On the record before us, one wonders how Glaxo could have been sure of what Crookes knew. Brereton, the Glaxo employee charged with initiating the application for the '431 patent, testified that he did not consult Crookes, the

named inventor, at any time. Instead, in accordance with Glaxo's standard patent policy, Brereton conferred with Crookes' superiors to obtain all of the information necessary to secure a patent on the invention. It strikes me as incongruous to rely on the inventor's actual knowledge here if Glaxo indeed thought that knowledge was so insignificant that it did not even merit consultation during preparation of the application.* At the very least, the district court should have given Novopharm the chance at discovery about just what Crookes in fact knew.

But I believe that even absent further discovery the district court could have found a best mode violation in this case. As the district court stated:

> [i]t is undisputed, however, Brereton and other officers within Glaxo believed azeotroping was the best mode of preparing ranitidine hydrochloride for pharmaceutical use, and Glaxo actually utilized this method in the commercial production of ranitidine hydrochloride. These officials within Glaxo made a deliberate choice not to reveal what they believed to be the best mode of making the patented invention, but instead to protect the knowledge as a trade secret.

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* The court finds comfort in the regulations requiring that the inventor sign an oath attesting that he has reviewed the application, 37 C.F.R. §§ 1.41(a), 1.51(a)(2) & 1.63(b)(1)(2), reasoning that Glaxo must have at least let Crookes review the application before it was filed, But none of these regulations speaks to the best mode requirement. Nor are we told how Crookes could sign such an oath if he was never consulted before the application was filed. Perhaps the court has hit upon grounds for a charge of inequitable conduct against Glaxo that everyone else missed.

830 F. Supp. at 881. This recitation suggests that Glaxo set out to isolate Crookes from any knowledge about the azeotroping technique specifically to avoid the best mode disclosure requirements. If true, these circumstances would justify imputing knowledge to Crookes from Brereton and the other Glaxo employees who acted as agents for Crookes during the application process. I would remand to allow the district court to make the necessary factual findings and decide whether to impute that knowledge.

Imputing knowledge to an inventor may be necessary under appropriate circumstances, to protect the public's "paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct." *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 816 (1945) (endorsing equitable doctrine of unclean hands in patent suits). "The possession and assertion of patent rights are 'issues of great moment to the public.' " *Id.* at 815. And the best mode requirement lies at the heart of this public interest. It is a vital part of the statutory *quid pro quo* that justifies a patent. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1210, 18 USPQ2d 1016, 1024 (Fed. Cir. 1991). In return for a seventeen year monopoly the patentee must disclose his invention to the public. But he must go beyond simply informing the public of the bare outlines of the invention. He must also tell what he believes to be the best embodiment of the invention, and he must do so in a way that allows the public to practice that embodiment. This prevents the inventor from obtaining patent protection with a minimal disclosure that

reveals only inferior forms of the invention, while retaining for himself the most advantageous modes of carrying the invention into practice. *In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA 1962). The court's pinched reading of the best mode requirement surely violates at least the spirit of this rule at the public's expense.

Imputing an agent's knowledge to the principal has sound roots in law and equity. An agent's acts and knowledge can be imputed to the principal when necessary to protect the interests of others, so long as the acts or knowledge in question fall within the scope of the agent's authority. Restatement (Second) of Agency, § 261 (principal liable for agent's fraud within scope of agency), § 274 (knowledge of agent acquiring property for principal imputed to principal); *see also American Soc. of Mechanical Engineers, Inc. v. Hydrolevel Corp.*, 456 U.S. 556, 566 (1982) (principal liable for antitrust violation based on agent's fraud within apparent authority). This precept is firmly rooted in patent law as well, in the traditional doctrine of inequitable conduct, whereby the inventor's duty to disclose material information to the Patent Office is extended to all those involved in the filing and prosecution of a patent application. *See* 37 C.F.R. § 1.56 (1994); *Fox Indus. v. Structural Preservation Sys.*, 922 F.2d 801, 804, 17 USPQ2d 1579, 1581 (Fed. Cir. 1990).

The fact that Crookes' agents knew about the process does not by itself justify imputing that knowledge to him. If he really was unfamiliar with the azeotroping process, that unfamiliarity may simply have resulted from the normal division of labor necessary within a large corporate enterprise. But the district court appears to have

inferred a darker subtext – that Glaxo may have deliberately set out to screen this inventor from the azeotroping technique to conceal the process for itself.

The problem is that Glaxo's version of best mode, which the court now adopts, would allow, if not encourage, employers to isolate their employee/inventors from research directed to finding the most advantageous applications for their inventions, knowledge that the inventors would probably have had but for the employer's efforts to keep the work secret. As a result, inventors may have only limited perspective on the real value of their inventions, and can accordingly share only this limited perspective with the public. All the while, the employer/assignee will have a view of the big picture, fully aware, through its other employees, of superior modes of practicing the invention. But the assignee will be under no obligation to disclose those modes to the public. This deliberate subversion of the statutory disclosure would deprive the public of the benefits of the best mode of practicing the invention. There is no reason why this court should condone such abuse of the public trust. *Cf. Precision Instrument Co.*, 324 U.S. at 815.

I would hold that if there truly was such a pattern of deliberate concealment of information that would otherwise have been known to the inventor, the knowledge of those who sought to conceal that information and who now attempt to enforce the patent may be imputed to the inventor. The district court can refuse to enforce the patent and should be given the opportunity to do so with a correct understanding of its powers.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NORTH CAROLINA

GLAXO, INC. and
GLAXO GROUP LIMITED,

Plaintiffs,

V.

NOVOPHARM LTD.,

Defendant.

JUDGMENT IN A CIVIL CASE

CASE NUMBER:
91-759-CIV-5-BO
Raleigh Division

(Filed Sep. 17, 1993)

[ ] **Jury Verdict.** This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

[X] **Decision by Court.** This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

IT IS ORDERED AND ADJUDGED that the defendant Novopharm Ltd. not be granted approval to sell Form 2 ranitidine hydrochloride prior to the expiration of the '431 patent. Defendant Novopharm is to refrain from the commercial manufacture or sale within the United States of Form 2 ranitidine hydrochloride prior to the expiration of the '431 patent and this case is hereby dismissed.

JUDGMENT FILED AND ENTERED THIS 17th DAY OF SEPTEMBER, 1993, AND COPIES MAILED TO:

Joseph W. Eason, Esq.
P. O. Box 26507
Raleigh, NC 27611

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September 17, 1993
Date

DAVID W. DANIEL
Clerk

/s/ Rebecca Bowen
(By) Deputy Clerk

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA RALEIGH DIVISION

No. 91-759-CIV-5-BO

GLAXO, INC. and GLAXO GROUP LIMITED, Plaintiffs, v. NOVOPHARM LTD., Defendant.	)	ORDER (Filed Sep. 17, 1993)

Plaintiff Glaxo Group Ltd. is the owner of the United States Patent No. 4,521,431 covering a particular crystalline form of a chemical compound called ranitidine hydrochloride.[1] The '431 patent expires in 2002. Plaintiff Glaxo Inc. is the United States subsidiary of Glaxo Group Ltd. and is the exclusive U.S. licensee of the '431 patent. Defendant Novopharm infringed this patent on August 9, 1991, by filing an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration in which it sought to market ranitidine hydrochloride beginning in 1995. Plaintiffs (hereinafter referred to collectively as Glaxo) then filed this action requesting an injunction barring further infringement by Novopharm. Novopharm filed an answer in which it admitted infringement, but raised as a defense that the patent was invalid.

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[1] Glaxo markets ranitidine hydrochloride as antiulcer medication under the brand name Zantac.

The case was tried to the court starting on August 9, 1993. At trial, Novopharm contended that the '431 patent is invalid for three reasons: (1) because the crystalline form claimed in the '431 patent was inherently anticipated by an earlier patent held by Glaxo, (2) because Glaxo engaged in inequitable conduct in the prosecution of the '431 patent, and (3) because Glaxo officials prosecuting the '431 patent failed to disclose the best mode of processing ranitidine chloride for pharmaceutical use. Evidence was presented on each of these issues, and based upon that evidence the court decides the issues.

I. FACTUAL BACKGROUND

A. The '658 Patent.

In 1976 Glaxo chemists in Great Britain discovered ranitidine, an aminoalkyl furan derivative with histamine blocking capabilities, and began preparations for manufacturing and selling ranitidine as an antiulcer drug. An application for a patent covering the compound was filed with the patent office in the United Kingdom in 1976.

During the patent application process, Glaxo chemists attempted to synthesize a ranitidine salt. Salts are generally the preferred form of a compound for use in pharmaceutical manufacturing. On June 27, 1977, David Collin, a chemist at Glaxo's laboratories in Ware, U.K., discovered a process for making ranitidine hydrochloride, a salt of ranitidine, and recorded the method he had discovered in his notebook.

On July 25, 1977, Glaxo filed an application for a U.S. Patent covering all ranitidine compounds of a specified

general formula, including ranitidine hydrochloride. That application resulted in the issue of United States Patent No. 4,128,658 (the '658 patent).

Claim 18 of the '658 patent covers ranitidine hydrochloride. The method for making ranitidine hydrochloride is set out at Example 32 of that patent. Example 32 was written based on Mr. Collin's work of June 27, 1977.

B. The '431 Patent.

From 1977 to 1980, Glaxo's Chemical Development Department tested procedures for the commercial production of ranitidine hydrochloride. The procedure set out in Example 32 was not used in any of this work. A somewhat similar process, known within Glaxo as Process 3A, was used during the early part of the scale-up work, and in 1979, a more efficient procedure known as Process 3B was substituted for Process 3A.

On April 15, 1980, for unknown reasons, the thirteenth batch of ranitidine hydrochloride prepared using Process 3B produced crystals that were different from those previously produced by Glaxo. The differences between the prior batches and Batch 3B13 were confirmed by two analytic processes, known as infra-red spectroscopy and x-ray powder diffraction. Based on these analyses Glaxo chemists concluded that there were two crystal forms of ranitidine hydrochloride. Glaxo chemists designated the form produced on April 15 as Form 2 and the form produced in all prior batches as Form 1.

Glaxo eventually decided to proceed with the commercial development of Form 2 rather than Form 1, and modified Process 3B so that it regularly produced Form 2. The modified Process 3B was designated Process 3C by Glaxo chemists, and has been used by Glaxo to manufacture all the ranitidine hydrochloride it has sold commercially.

On October 1, 1980, Glaxo filed a U.K. patent application covering Form 2. This application was prosecuted for Glaxo by Elkington and Fife, a firm of patent agents in the United Kingdom. In 1981, Glaxo filed a U.S. patent application covering Form 2, naming as the inventor Dr. Derek Crookes, the chemist who was in charge of the Chemical Development Department in 1980 when the first Form 2 was produced.

The patent examiner initially rejected the claims of Glaxo's Form 2 application and again rejected them on reconsideration. Grounds for the rejection were stated as "anticipated by or, in the alternative, . . . obvious over" the '658 patent, referring specifically to Example 32.

In response to this rejection, Glaxo submitted two declarations which purported to show distinctions between the claims in the application and the prior art. After receiving these declarations, the examiner withdrew his rejections, and U.S. Patent No. 4,521,431 was issued, covering Form 2 ranitidine hydrochloride as characterized by its infra-red spectrum (Claim 1) and its x-ray powder diffraction pattern (Claim 2). In addition, the patent covers certain pharmaceutical compositions (Claims 3-16) and treatment methods (Claims 17 and 18) using Form 2.

II. NOVOPHARM'S DEFENSES

As noted above, Novopharm admits that by filing its ANDA in 1991 it infringed on the '438 patent, but raises in defense its contentions that the patent is invalid. There is a statutory presumption that an issued patent is valid, 35 U.S.C. § 282, and the party challenging the patent bears the burden of proving invalidity by clear and convincing evidence. *Ethicon, Inc. v. Quigg*, 849 F. 2d 1422 (Fed. Cir. 1988). Keeping these standards in mind, the court now turns to a discussion of Novopharm's challenge to the validity of the '431 patent.

A. Inherent Anticipation.

Under 35 U.S.C. § 102, an invention may be patented only if it is "novel." Novelty is judged by examining the "prior art" available to the public at the time the patent application is filed. The prior art includes the teaching from an existing patent such as the '638 patent in this instance. *Graham v. John Deers Co.*, 383 U.S. 1, 6 (1966). If a unit of prior art discloses an invention, then the invention is said to be "anticipated" by the prior art. *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444 (Fed. Cir. 1984). The prior art need not expressly disclose the invention.

If an inventor seeks to claim an advantage or modification that flows necessarily from a prior art reference, the reference inherently anticipates the inventor's claim, *Stoller v. Ford Motor Co.*, 18 U.S.P.Q.2d 1545, 1547 (Fed. Cir. 1991), even if the advantage was not appreciated by

the inventor of the prior art. *In re Sovish*, 769 F.2d 738 (Fed. Cir. 1985).

In order for a claim to be inherent in the prior art it is not sufficient that a person following the disclosure sometimes obtain the result set forth in the claim, it must invariably happen. *Standard Oil v. Montedison*, 664 F.2d 356, 372 (3rd Cir. 1981).

Novopharm contends that Form 2 ranitidine hydrochloride, claimed in the '431 patent, is inherent in Example 32 of the '658 patent. As noted, Example 32 describes a process for making ranitidine hydrochloride, and was written based on David Collin's experiment of June 27, 1977, recorded in his notebook at page 122.[2]

In layperson's terms, the example tells a chemist to dissolve ranitidine base in industrial methylated spirit (IMS) (a solvent made up largely of ethanol) containing

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[2] The example reads:

EXAMPLE 32

N-[2-[[[5-(Dimethylamino)methyl-2-furanyl] methyl]thio]ethyl]-N'-methyl-2-nitro-1, 1-ethynediamine hydrochloride

N-[2-[[[5-(Dimethylamino)methyl-2-furanyl] methyl]thio]ethyl]-N'-methyl-2-nitro-1, 1-ethynediamine hydrochloride was dissolved in industrial methylated spirit 74 o.p. (200 ml) containing 0.16 of an equivalent of hydrogen chloride. Ethyl acetate (200 ml) was added slowly to the solution. The hydrochloride crystallized and was filtered off, washed with a mixture of industrial methylated spirit 74 o.p. (50 ml) and ethyl acetate (50 ml) and was dried at 50. The product (50 g) was obtained as an off-white solid m.p. 133 - 134.

hydrogen chloride gas, then to add ethyl acetate, which is a cosolvent to aid in crystallization. As a result, crystals of ranitidine hydrochloride will form and precipitate from the solution. The crystals are then filtered out and dried.

It is Novopharm's theory that when the Example 32 procedure is faithfully followed, the product is, and always was, Form 2 ranitidine hydrochloride. Novopharm does not dispute that Mr. Collin performed the work shown in his notebook on page 122, or that his work produced Form 1.

Instead, Novopharm claims that Example 32 as written omits two critical and material steps that Mr. Collin included in his experiment on page 122. Consequently, Novopharm claims that when the prior art, Example 32, is practiced exactly as written, without the critical extra steps taken by Collin during his experiment of June 27, 1977, the product is always Form 2.

Simply put, Novopharm claims Glaxo *never* performed Example 32 precisely as written either before or after including it in the '638 patent. Novopharm theorizes if Glaxo had properly performed the example, the result would have been Form 2.

Novopharm claims that in reality it was the first party to faithfully practice Example 32. Novopharm contends the results of such practice under the prior art led Novopharm to the conclusion that Form 2 was anticipated by the '658 patent add, consequently, this conclusion led Novopharm to the filing of its ANDA application in 1991.

In support of this contention, Novopharm called as witnesses four chemists.[3] Novopharm contends the chemists repeatedly followed the Example 32 procedure and always achieved Form 2. These results were tested by infrared and x-ray spectroscopy. It is not disputed that the experiments Novopharm's witnesses ran did in fact produce Form 2. This, Novopharm argues, proves that Example 32, faithfully practiced, always results in Form 2. Based on this evidence, Novopharm seeks a finding that the '658 patent inherently anticipated Form 2 when Glaxo applied for the patent in 1977.

Glaxo attacked the validity of the results obtained by Novopharm's witnesses. Glaxo charges that Novopharm's experiments were contaminated with "seed" crystals of Form 2, and therefore, were not faithful replications of Example 32. Glaxo claims Novopharm's experiments were exposed to seeding from existing form 2 crystals and are unreliable; one, because either the ranitidine base used by Novopharm's scientists was impure, or two, because of airborne or surface seed contamination in the environment within which the experiments were conducted.

In all but one of the Novopharm experiments, the ranitidine base used as a starting material was synthesized by taking Form 2 ranitidine hydrochloride and using sodium hydroxide to "free" the base from the salt. Glaxo claims it is scientifically impossible through this

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[3] The four chemists were Ildiko Riss, a research chemist at Novopharm, Dr. Xianglang Lu of Northwestern University, Dr. John Belletire of the University of Chicago, and Dr. Natalie Lazarowich of Dalton Chemical Laboratories in Toronto.

reduction procedure to remove all traces of Form 2 from the base and that seed crystals would necessarily remain.

A number of Novopharm experiments were conducted in areas where Form 2 ranitidine hydrochloride had been used, handled or manufactured. Glaxo contended that because submicroscopic seed crystals in these areas contaminated the environment this would inevitably be present in the air and on surfaces. Thus, the seed crystals would come in contact with the reaction mixture and affect the outcome of Novopharm's experiments.

Novopharm's witnesses insisted they had taken precautions to avoid seeding, and Doctors Lu and Belletire conducted their experiments in environments where only trace amounts of ranitidine hydrochloride, if any, had been present.

Dr. Lazarowych testified that because ranitidine hydrochloride is highly soluble in water and the method used for extracting the base from Form 2 required dissolving the salt in water, no ranitidine hydrochloride seeds could have survived the conversion to ranitidine base. Further, she testified with regard to experiments conducted in a "glove bag." There, extraordinary precautions were taken to avoid any potential for the introduction of airborne seeds. The court found this testimony credible, and finds that Novopharm's experiments were not affected by seeds of Form 2. Accordingly, Novopharm's evidence established that each time their witnesses practiced Example 32, the product was Form 2 ranitidine hydrochloride.

In response to this showing, Glaxo called David Collin. Collin testified that the work recorded in his notebook at page 122 was the basis for Example 32, and that infrared spectroscopy established the product of the page 122 experiment as Form 1. Novopharm contends that two of the steps Collin took were not reflected in Example 32 as written. First, the Collin experiment shown on page 122 contained a warming step not reflected in Example 32. Second, the notebook reflects Collin's reaction mixture as slightly acidic.

While it is true that neither warming nor variations in pH are addressed in the express language of Example 32, Collin testified to the example as an accurate summary of his work. He further testified that the differences in temperature and pH not shown in the examples were only very slight, and that he did not believe these differences would affect the polymorphic form produced from practicing Example 32. The court found this testimony to be both credible and supported by other evidence presented during the trial.

With respect to the use of gentle heat, all of the expert chemists who testified for both sides, with the exception of Dr. Lazarowych, told the court it is acceptable practice, when dissolving a solid, to warm the mixture to bring the solid into the solution. Although she felt heat would generally be acceptable, Dr. Lazarowych testified such a process would be undesirable in this particular experiment because of the structure of the ranitidine molecule. Despite this belief, she used heat during her glove bag experiments to speed the dissolution process. The court finds the warming process is acceptable to a chemist skilled in the art while practicing Example 32.

With respect to the differences in pH, the court holds credible Collin's testimony that the pH of the experimental solution was slightly acidic. The evidence was that a chemist skilled in the art would not consider a slight excess of acidity to be outside the teachings of Example 32. The science of chemistry recognizes such minute variation may occur in the amounts and proportions of the ingredients when mixing an acid and a base, and therefore, some minor variation in pH is tolerated under the method used in Example 32 to produce the salt. The court finds the example not to require the reaction mixture to have a completely neutral pH prior to crystallization.[4]

The court finds from the evidence that Example 32 is an accurate description of Collin's work. On June 27, 1977, Collin performed an experiment following a process later recorded in the '658 patent as Example 32. The product of this experiment was Form 1 ranitidine hydrochloride.

Glaxo called as witnesses three chemists from Oxford University, who testified that after the commencement of

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[4] Dr. Lazarowych presented her theory to the court that minor differences in pH when coupled with heat would affect the crystalline form resulting from the experiment. Because of the structure of the ranitidine molecule, she believes that ranitidine degrades after the application of slight heat within certain pH ranges, resulting in a different crystalline form when the reaction is complete. After weighing this testimony against that of other witnesses, the court is not persuaded that Novopharm made a sufficient showing on this point to prove by clear and convincing evidence that slight variations in temperature and pH in Mr. Collin's experiment would result in an entirely different polymorph from the practice of otherwise identical experiments.

this lawsuit they had prepared ranitidine base using one of the methods set out in the '638 patent. They then used this base as the starting material in three replications of Example 32. In each of these experiments, the product obtained was Form 1. This work, Glaxo contended, shows that when Example 32 is performed, the product of such example is Form 1.

Novopharm challenged the validity of the Oxford work. In one of the Glaxo experiments, Dr. Crouch testified that he seeded the solution with Form 1 crystals to induce crystallization. In a second experiment, he sought to induce crystallization by scratching the wall of his reaction vessel with a glass rod covered with some ranitidine base. The third experiment followed Example 32 closely except that the reaction vessel was warmed.

While the court agrees the first two of Dr. Crouch's experiments were contaminated by the introduction of Form 1 seeds and ranitidine base, the same is not true of his third experiment. Dr. Crouch was credible in his testimony that he only applied gentle heat to the reaction vessel in his third experiment to aid in the dissolution of the ranitidine base. The court finds that gentle warming is within the proper practice of Example 32.

Based upon these findings, the court concludes that Collin's experiment and Dr. Crouch's third experiment would both be considered by a chemist skilled in the art to be within the teachings of Example 32. When this conclusion is coupled with the court's findings concerning Novopharm's experiments above, the evidence as a whole shows that the proper practice of Example 32 has resulted at times in the exclusive production of Form 1

and at other times in the exclusive production of Form 2. The only practice of Example 32 at the time the '658 patent was issued was Collin's page 122 experiment, and that clearly produced Form 1. The evidence does not support a finding that Form 2 invariably results from the practice of Example 32. "Inherency is not established by possibilities or probabilities. The mere fact that certain things may result from a given set of circumstances is not sufficient." Rosenberg, *Patent Law Fundamentals* §7.04. Novopharm has failed to carry its burden of proving inherency by clear and convincing evidence.

B. Inequitable Conduct.

Novopharm's second ground for contending the '431 patent is invalid is their contention that Glaxo was guilty of inequitable conduct. In order to render a patent unenforceable on the grounds of inequitable conduct, a party must show by clear and convincing evidence that the patentholder made a material misrepresentation to the patent office during the patent prosecution process, and that the misrepresentation was intentional. *Schering Corp. v. Optical Radiation Corp.*, 867 F.2d 1292 (Fed. Cir. 1989).

Novopharm's charges of inequitable conduct stem from the submission of two declarations in response to the patent examiner's August 28, 1983 rejection of Glaxo's Form 2 patent application. In that rejection, the examiner said

> Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as anticipated by, or as being obvious over, Price et al 4,128,658. Price et al discloses (example 32) and claims (claim 18) [ranitidine].

> The present claims are drawn to a specific form of this compound. Applicant's argument have [sic] been carefully considered [sic]. However, absent a verified showing with a full explanation of the data, no patentable difference in structure is seen. Further, a mere difference in physical form absent a showing of unexpected properties does not establish a patentable distinction.

In response to this rejection, Glaxo submitted declarations to the patent office from John Harold Hunt, the head of Glaxo's Spectroscopy Unit, and David Trevor Collin, a research leader in the company's Chemical Development Department. Novopharm contends both of these declarations contain intentional misrepresentations of material fact.

1. The Hunt Declaration.

Dr. John Harold Hunt's declaration set out the comparative results of certain analytical tests run on samples of Form 1 and Form 2 ranitidine hydrochloride. Dr. Hunt represented to the examiner that

> 3. Under supervision and/or at my direct request, the product of Example 1 of the present application i.e. Form 2 ranitidine hydrochloride and the product of Example 32 of US Patent 4128658 i.e Form 1 ranitidine hydrochloride have been examined using infra-red, n.m.r. and x-ray powder diffraction studies, and the results of these studies are reported below.

* * *

5. Accompanying this declaration as Exhibit JHH 1 is a copy of the infrared spectrum . . . of Form 1 ranitidine hydrochloride. This is the material prepared according to Example 32 . . .

* * *

7. The infrared spectra for Form 1 and Form 2 ranitidine hydrochloride were obtained in my Spectroscopy unit and the differences in main peak positions are such that it is clear that in the solid state the two products are not the same.

8. The present application also gives at page 4 'd' spacings obtained from the x-ray diffraction pattern for form 2 ranitidine hydrochloride . . . a comparison of this data with data obtained for Form 1 ranitidine hydrochloride by the same method is as follows:

[Table showing comparisons is omitted]

9. . . . From a comparison of the respective 'd' spacings it is clear that there are very obvious and significant differences that confirm that in the solid state the two products do not have the same crystal structure.

Glaxo has stipulated that the infrared spectrum produced as Exhibit JHH1 with the Hunt Declaration was in fact *not* the result of a test run on a sample of Form 1 produced by Example 32; the sample tested in JHH1 was prepared using Process 3A. It is also stipulated that no x-ray powder diffraction study was ever performed on a sample produced by the Example 32 process. Based on these facts, Novopharm argues that submission of the Hunt declaration constituted inequitable conduct.

On rebuttal, Glaxo produced evidence that Exhibit JHH1, although not prepared from an Example 32 sample, was identical to the spectrum prepared from Collin's experiment on page 122 of his notebook, and was the same within scientific tolerances as all of the approximately one hundred and twenty five infrared spectra prepared from Form 1 samples. It was established by expert testimony that although x-ray powder diffraction can more accurately identify different crystalline forms, infrared spectroscopy is a good indicator of differences between polymorphs. For this reason, fewer x-ray powder diffraction studies were run by Glaxo, but the results of all the studies performed on Form 1 produced by means other than Example 32 were the same. Based upon this showing, Glaxo argued that there was no evidence of any material misrepresentation and no showing of intent to deceive the patent examiner.

There is no doubt that the Hunt declaration is misleading. The declaration represents that Exhibit JHH1 was prepared from an Example 32 sample. It was not appropriate to submit a spectrum prepared from a sample of any other process. The declaration also represents that "the product of Example 32" was subjected to x-ray powder diffraction, and this was in fact not true. These misstatements only constitute inequitable conduct, however, if they were material and were submitted with intent to deceive the patent examiner.

Turning first to materiality, the court finds the misstatements were material. The patent examiner asked specifically for data showing the differences between the product of Example 32 and Form 2. The Hunt declaration purported to address that concern directly, but it did not.

"[T]here is no room to argue that the submission of false affidavits is not material." *Rohm & Haas Co. v. Crystal Chemical Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983), *cert. denied* 469 U.S. 851 (1984).

In order to carry its burden on the element of intent, Novopharm urges the court to infer the necessary scienter from the circumstances surrounding the submission of the Hunt Declaration. Although circumstantial evidence and the context in which an affidavit is submitted may prove state of mind, *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182 (Fed. Cir. 1993), the facts of this case do not warrant an inference of fraudulent intent.

While the court did not have the benefit of testimony from Dr. Hunt,[5] it is clear from the evidence that as head of the Spectroscopy Unit, he knew the infrared spectroscopy results of over one hundred Form 1 analyses had been the same. All of those analyses had shown different patterns than Form 2. Dr. Hunt also knew that the product of the very experiment on which Example 32 was based had been tested, and had produced results consistent with all other Form 1 infrared spectra.[6]

Considering Dr. Hunt's declaration in light of this knowledge, the court finds that the evidence does not

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[5] Dr. Hunt passed away in 1985.

[6] Even if the court accepted Novopharm's argument that the experiment on Collin's page 122 is not consistent with Example 32, there is no evidence that Dr. Hunt or anyone else at Glaxo suspected that there was any significant difference between the patent example and the work on which it was based.

support the inference that Dr. Hunt and the plaintiff intended to deceive the patent examiner by submitting Exhibit JHH1. Since the Example 32 data the examiner requested was identical to the 3A spectrum produced as Exhibit JHH1, neither Glaxo nor Dr. Hunt could have had anything to gain from the submission of the improperly identified exhibit.

With respect to the x-ray powder diffraction data, the court finds Novopharm has failed to show intent to deceive by clear and convincing evidence. The differences between Forms 1 and 2 of ranitidine hydrochloride are evident from infrared spectroscopy alone, and the powder diffractions, run on the two forms, confirmed the distinctions between the two polymorphs. Dr. Hunt had seen no differences in the infrared data between the product of Example 32 and other Form 1, and had no reason to believe that the x-ray data would differ, either. The court does not infer fraudulent intent from his submission of x-ray data from samples not prepared using Example 32.

Based on these findings, the court holds that Novopharm has failed to carry its burden of proving that Glaxo's submission of the Hunt Declaration constituted inequitable conduct in the prosecution of the '431 patent.

2. The Collin Declaration.

In addition to the Hunt Declaration, Glaxo submitted to the patent office in 1983 the affidavit of David Trevor Collin, a Research Leader in Glaxo's Chemical Development Department. In this declaration, Collin represented to the examiner that Form 2 had certain qualities which

made it less difficult and expensive to manufacture than the prior art. The first of these representations was that the Example 32 process requires the use of hydrogen chloride gas, which is corrosive, awkward to handle, and difficult to contain. By contrast, Collin's declaration says

> [Form 2] can most satisfactorily be prepared and isolated in a crystalline form in the presence of concentrated hydrochloric acid. This is surprising since ranitidine hydrochloride is sensitive to moisture and more significantly is highly soluble in water. The fact that Form 2 ranitidine hydrochloride can be prepared using concentrated hydrochloric acid is a very important and most significant factor since it avoids the need to use hydrogen chloride gas and the attendant problems thereof.

Secondly, Collin represented to the examiner that

> [M]y opinion, based on experience with the processes for preparing both Form 1 and Form 2 ranitidine hydrochloride, is that the product (Form 2) obtained from concentrated hydrochloric acid and isopropanol has better drying and filtration characteristics than the product (Form 1) obtained from the process using hydrogen chloride in industrial methylated spirit and ethyl acetate.

It is undisputed that between 1979 and 1980 Glaxo regularly prepared Form 1 using Process 3B, which requires the use of hydrochloric acid and isopropanol. From this fact, Novopharm argues the Collin Declaration is fraudulent because it suggests Form 1 cannot be made using hydrochloric acid, and that the ability to use hydrochloric acid is a distinguishing feature between the two

polymorphs. Moreover, Novopharm contends Collin never compared the filtration and drying characteristic of Form 2 ranitidine hydrochloride with the product of Example 32.

On rebuttal, Glaxo called Collin as a witness. He testified that at the time of the '658 patent application in 1977, and for some time after, Glaxo chemists were convinced that aqueous hydrochloric acid could not be used in the manufacture of ranitidine hydrochloride because the crystals were highly soluble in water. He further testified that his intent in preparing his declaration was to compare the art revealed in the '658 patent with Form 2. Since the ability to use hydrochloric acid was not known in 1977, it was indeed surprising when compared to the prior art. Collin also testified that because Form 2 hydrochloride crystals are needlelike and Form 1 crystals are flatter and less three dimensional, Form 2 can be filtered and dried much more easily than Form 1, especially the Form 1 prepared using Process 3A.

The court found Collin's testimony credible on these points. Example 1 of the '431 patent discloses the ability to use hydrochloric acid to make Form 2 ranitidine hydrochloride; the prior art of Example 32 discloses the ability to make ranitidine hydrochloride using hydrogen chloride in IMS. This difference between the '431 patent and the prior art is significant. The evidence justifies Collin's conclusion that the ability to use aqueous hydrochloric acid was a surprising development over the prior art. There is no dispute that Form 2 has improved drying and filtration characteristics over Form 1 prepared using industrial methylated spirits and hydrogen chloride. Based upon these findings, the court concludes Collin

made no misrepresentations of fact in his declaration. The submission of his declaration to the patent office cannot be the basis for a finding of inequitable conduct.

C. Failure to Disclose the Best Mode.

Novopharm's third reason for arguing the '438 patent be invalidated is its contention Glaxo failed to disclose the best mode of manufacturing Form 2 ranitidine hydrochloride for pharmaceutical use. The patent statutes require, in addition to disclosing the invention itself, the applicant disclose in the patent specifications the best mode for making and using the claimed invention. 35 U.S.C. § 112. The purpose of this requirement is to assure that in exchange for the monopoly protection extended by the grant of the patent, the applicant has given the public full access to the invention once the monopoly's protection is gone. *See Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1210 (Fed. Cir. 1991).

The only evidence Novopharm presented on its best mode defense was the testimony of Graham George Brereton, who was the Glaxo employee responsible for directing the prosecution of the '431 patent.[7] Brereton testified that prior to initiating the patent application, he met with research scientists within Glaxo to discuss what would be included in the patent specifications.

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[7] Mr. Brereton was called by Novopharm as a hostile witness.

At the time of this meeting, Glaxo scientists recognized that ranitidine hydrochloride had poor flow properties and was therefore difficult to measure and dispense accurately in its pure form. In order to address this problem, Glaxo scientists had developed an "azeotroping" process by which ranitidine hydrochloride was granulated. Because granulation made ranitidine hydrochloride easier to measure and dispense accurately, azeotroping made it much simpler to formulate the salt into tablets, capsules and other pharmaceutical compositions. The azeotroping technique was a novel one, however, and Glaxo wished to retain it as a trade secret within the company.[8]

Having been told of this novel azeotroping process that Glaxo wished to keep private, Brereton wrote to Glaxo's British patent agent, James Marchant, and informed him that he believed the best mode requirement in the United States would require Glaxo to disclose the azeotroping procedure if it included pharmaceutical composition claims in its U.S. patent application. In order to avoid the requirement that azeotroping be disclosed, he asked that no pharmaceutical composition claims be filed in the British patent application, so the two patents would be consistent. Because of this request, Marchant did not, at first, pursue composition claims in the British or American patent applications.

In October of 1982, Brereton left his position as patent officer to take another job within Glaxo. On July 3,

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[8] Glaxo filed a British patent application covering the azeotroping process, but eventually abandoned that application without ever making the process public.

1984, Glaxo amended its U.S. patent application covering Form 2 to include pharmaceutical composition claims, including tablets and capsules. The amendments did not reflect, however, that these compositions could best be made by utilizing the azeotroping technique.

It was Glaxo's contention at the close of Novopharm's evidence, the above showing was insufficient as a matter of law to establish a defense of invalidity in this case for two reasons. First, the only claims of the patent in suit infringed by Novopharm's ANDA were Claims 1 and 2, covering ranitidine hydrochloride, generally. The pharmaceutical composition claims were not in issue, and therefore, even if there was a best mode violation concerning pharmaceutical compositions, Glaxo contends, it is not relevant in this case. Secondly, Glaxo argued even if others within Glaxo believed azeotroping was the best mode for using Form 2 ranitidine hydrochloride, Novopharm presented no evidence Dr. Derek Crookes, who is listed as the inventor of Form 2, knew of this best mode or attempted to conceal it.

The court finds the first of these arguments unavailing. The best mode requirement imposes a duty to disclose not only the best mode of *making* the invention, but the best method of *using* it. *Chemcast Corp. v. Arco Industries Corp.*, 913 F.2d 923, 927 (Fed. Cir. 1990); *Refac International Ltd. v. IBM*, 689 F. Supp. 422, 431 (D.N.J. 1988). Here, ranitidine hydrochloride is used not as a raw material, but as a drug administered to patients by means of some pharmaceutical composition. The court holds the failure to disclose the best mode of producing ranitidine hydrochloride for pharmaceutical use would affect the validity of claims covering the raw material.

With respect to the second of Glaxo's arguments, however, the court believes on the facts of this case, precedent dictates a finding of no best mode violation. In *Texas Instruments v. International Trade Commission*, 871 F.2d 1054 (Fed. Cir. 1989) the Federal Circuit upheld a finding that Texas Instruments had not violated the best mode requirement by failing to disclose a preferred method for boosting voltage on certain computer components on which it owned a patent. In that case the manufacturing group had developed a best mode which the company used commercially, but the person named as the inventor did not know of or conceal this best mode. The court found that the absence of a showing of actual knowledge by the inventor was dispositive of the defendant's best mode argument. *Id.* at 1061.

In the instant case, Brereton testified Dr. Derek Crookes, who was listed as the inventor in the patent, was not consulted in making this decision, and it was his belief Crookes did not know the azeotroping procedure was the best mode for manufacturing ranitidine hydrochloride for pharmaceutical use. The court found Brereton to be a credible witness, and therefore, cannot find as a fact Crookes knew azeotroping was the preferred mode or attempted to conceal such preferred mode in the '431 patent application. It is undisputed, however, Brereton and other officers within Glaxo believed azeotroping was the best mode of preparing ranitidine hydrochloride for pharmaceutical use, and Glaxo actually utilized this method in the commercial production of ranitidine hydrochloride. These officials within Glaxo made a deliberate choice not to reveal what they believed

to be the best mode of making the patented invention, but instead to protect the knowledge as a trade secret.[9]

Novopharm argued at trial that the knowledge of Glaxo officials directly connected to the application for the patent should be imputed to Crookes for purposes of finding a best mode violation. This argument has some intuitive appeal, since it is Glaxo, and not Crookes individually, that both directed the patent prosecution and has enjoyed the monopoly the issued patent provides. If the court were to impute to Crookes the knowledge of Brereton and those with whom he met prior to the patent application process, then clearly the court would be required to find a best mode violation.

The statute refers only to the knowledge of the inventor, however, 35 U.S.C. § 112, and the holding of the Federal Circuit in the *Texas Instruments* case does not permit using imputed knowledge to meet the requirement. The court concludes as a matter of law Novopharm failed to show the '431 patent should be invalidated based on a best mode violation.

III. CONCLUSION

Based on the evidence, Novopharm has failed to carry its burden on the defense of invalidity. The court holds that United States Patent No. 4,521,431 is not invalid, and that Novopharm infringed the patent by

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[9] Because none of Novopharms's evidence on its best mode defense was disputed, the court ruled at the close of Novopharm's case-in-chief that the best mode issue would be decided as a matter of law at the conclusion of the trial.

filing its ANDA on August 9, 1991. On this finding, it is ORDERED pursuant to 35 U.S.C. § 271 (e)(4) Novopharm not be granted approval to sell Form 2 ranitidine hydrochloride prior to the expiration of the '431 patent. Defendant Novopharm is further ORDERED to refrain from the commercial manufacture or sale within the United States of Form 2 ranitidine hydrochloride prior to the expiration of the '431 patent.

ORDERED this 17th day of September, 1993.

/s/ Terrence W. Boyle
TERRENCE W. BOYLE
UNITED STATES DISTRICT JUDGE

(SEAL)

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

94-1026

GLAXO INC. and GLAXO GROUP LIMITED,

Plaintiffs-Appellees,

v.

NOVOPHARM LTD.,

Defendant-Appellant.

ORDER

United States Court of Appeals
for the Federal Circuit

ORDER

(Filed Jun. 21, 1995)

A combined petition for rehearing and suggestion for rehearing in banc having been filed by the APPELLANT, and a response thereto having been invited by the court and filed by the APPELLEE, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on June 28, 1995.

Circuit Judge CLEVENGER did not participate in the vote.

FOR THE COURT,
FRANCIS X. GINDHART, CLERK

Dated: June 21, 1995

By /s/ Diane M. Frye
Diane M. Frye
Chief Deputy Clerk

cc: ROBERT F. GREEN
STEPHEN B. JUDLOWE

GLAXO INC V. NOVOPHARM, 94-1026
(DCT - 91-CV-759)

****

Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

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No. 95-477

Supreme Court, U.S.
FILED
OCT 20 1995
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

NOVOPHARM LTD.,

Petitioner,

—v.—

GLAXO, INC. and GLAXO GROUP LIMITED,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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COUNTER STATEMENT OF QUESTIONS PRESENTED

1. Were the District Court and the Court of Appeals for the Federal Circuit correct in finding that the best mode requirement of 35 U.S.C. § 112 is not violated when the *inventor* (vis-a-vis others at the corporate assignee) did not know of a preferred way of formulating the active ingredient for an anti-ulcer medicine (the claimed subject matter) into tablets when:

(i) the *statute* by its express terms is directed to only the inventor's knowledge*;

(ii) the comparable provisions of prior statutes were specific only to the *inventor's* knowledge (Court of Appeals Decision at A.13a** and its f.n. 6);

(iii) Repeated authorities had explained and held that the best mode requirement addresses the subjective intent of *the inventor* (A.11a-15a); and

(iv) Congress "was aware of the differences between inventors and assignees", *see* 35 U.S.C. §§ 100(d) and 152, and it specifically limited the best mode required to that contemplated by the inventor. The Courts "have no authority to extend the requirements beyond the limits set by Congress." (A.11a-19a).

2. Was petitioner Novopharm denied due process when the Court of Appeals referred to the Declaration of the inventor of the patent in suit, Dr. Derek Crookes, filed in opposition to a pretrial motion of Novopharm when:

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* 35 U.S.C. § 112 provides in pertinent part:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, . . . and shall set forth the best mode contemplated by the *inventor* of carrying out his invention." (emphasis added).

** References in this form are to the Appendix attached to Novopharm's Petition for a Writ of Certiorari.

(i) *Petitioner Novopharm* raised the Declaration in *its* brief on appeal before the Federal Circuit, and that Court's Opinion corrected/disagreed with the way Novopharm characterized the substance of the Declaration;

(ii) The Declaration did not form any part of the District Court's decision of the case; and

(iii) The Federal Circuit's discussion of the Declaration is not a necessary part of its decision of the case.

3. Was petitioner Novopharm denied due process when the District Court denied Novopharm a deposition of the inventor of the patent in suit with respect to the supposed best mode violation when:

(i) Novopharm noticed the deposition for the weekend before trial—after having had the underlying documents supporting its supposed best mode violation for over two months;

(ii) Novopharm's notice of deposition in the United States of the United Kingdom resident inventor was in clear violation of Rule 26(a), 34(b), and 45(c)(3)(A)(ii) of the Federal Rules of Civil Procedure.

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INTRODUCTION

Respondents, Glaxo, Inc. and Glaxo Group Limited (hereinafter referred to collectively as "Glaxo") submit this Brief in Opposition to the Petition for Writ Of Certiorari submitted by Novopharm Ltd. (hereinafter referred to as "Novopharm").

SUMMARY OF REASONS FOR DENYING NOVOPHARM'S PETITION FOR WRIT OF CERTIORARI

1. The District Court and Court of Appeals for the Federal Circuit correctly applied the explicit provisions of 35 U.S.C. § 112, first paragraph, and a significant body of consistent authority construing that statutory provision, in requiring that an inventor alone must know of and conceal a "best mode" for practicing his invention before the statute is violated.

2. Petitioner-defendant Novopharm was not denied due process:

(a) in being denied a deposition notice only the weekend before trial after being possessed of documents which raised the issues sought to be pursued months prior, and where the deposition of the United Kingdom resident was noticed for a situs violative of Rules 26(a), 34(b) and 45(c)(3)(A)(ii) of the Federal Rules of Civil Procedure; and

(b) by reference in the Federal Circuit's affirming opinion to a Declaration not in the trial record where no use at all was made of that Declaration by the District Court in deciding the case, where the Federal Court disagreed with *Petitioner's* characterization of the Declaration in *Petitioner's* brief on appeal, and where the reference is not essential to the Federal Circuit's affirmance.

COUNTER STATEMENT OF THE CASE

Respondent-plaintiff Glaxo Group Ltd., a major United Kingdom-based pharmaceutical concern, is the owner of United States Patent No. 4,521,431 ("the '431 patent") covering a particular crystalline form of a chemical compound called ranitidine hydrochloride.[1] Respondent-plaintiff Glaxo Inc. is the exclusive U.S. licensee of the '431 patent.

Petitioner-defendant Novopharm, a Canadian generic drug vendor, infringed the '431 patent by filing an Abbreviated New Drug Application (ANDA) with the Federal Food and Drug Administration seeking to market ranitidine hydrochloride beginning in 1995 before the '431 patent expires. Plaintiffs (hereinafter referred to collectively as "Glaxo") then filed this action requesting an injunction barring further infringement by Novopharm.

Novopharm filed an Answer asserting a number of affirmative invalidity defenses including obviousness, anticipation, and a violation of the best mode requirement. To extricate itself from jointly litigating with another Canadian generic drug company, a defendant in an earlier filed case also seeking to invalidate the '431 patent under the Waxman-Hatch Act, and to obtain an expedited and earlier trial, Novopharm waived all affirmative defenses except anticipation.[2] As Novopharm characterized its "one issue", "streamlined" case:

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[1] Glaxo markets the patented polymorphic form of ranitidine hydrochloride as an anti-ulcer medication under the brand name Zantac®. Zantac® is the world's largest selling prescription drug.

[2] This strategy appears to be driven by Novopharm's desire to deny Genpharm Pharmaceuticals (the other generic drug company contesting '431) the possibility of completing a trial on the '431 patent and obtaining a judgment before Novopharm. Novopharm hoped thus to prevent Genpharm from claiming the exclusive right to market generic ranitidine hydrochloride for the six month period provided to Genpharm under 21 U.S.C. § 355(j)(4)(B)(iv) if Genpharm invalidated the '431 patent before Novopharm did.

> Novopharm's defense to Glaxo's infringement charge is based on invalidity of the claims of the '431 patent for double patenting under 35 U.S.C. § 101 and/or anticipation under 35 U.S.C. § 102(a), (b) and (e). Each of these defenses, however, turns on a single factual issue—whether when Example 32 of Glaxo's U.S. Patent 4,128,658 ("the '658 patent") is performed, the ranitidine hydrochloride claimed in claims 1 and 2 of the '431 patent is produced. If that question is answered in the affirmative, Novopharm wins; if it is not, Glaxo wins.

(Emphasis added).

This "one issue" case didn't last long in that posture. Novopharm quickly realized from the Glaxo documents obtained in its discovery that Example 32 was not a theoretical or paper example but, rather, represented actual experience, and that the Example had *not* produced the crystalline compound of the '431 claims, thus eviscerating Novopharm's anticipation defense. Novopharm's prospects on "inherency" invalidation were thus dim. Novopharm thereafter amended its defenses—first to add supposed inequitable conduct, and then to reintroduce best mode.

The case was tried in a two week bench trial beginning August 9, 1993 on the three affirmative patent invalidity defenses. Following Novopharm's evidence in its case-in-chief, Glaxo moved under Rule 52(c), Fed.R.Civ.P., *inter alia*, for a dismissal of the best mode defense. The District Court decided that it would:

> withdraw the best mode defense from the trial and make a ruling on that as a matter of law.
>
> I need an opportunity to further examine the law. If the defendants—if the plaintiffs are correct with respect to the claims and the knowledge of the inventor, then they would be entitled to a judgment as a matter of law on the facts in this case, and I just need to decide and resolve the status of the law in that regard.

After trial, the District Court ruled against Novopharm on each defense, and enjoined prospective infringement.

The Court of Appeals for the Federal Circuit affirmed, rejecting the best mode and other affirmative invalidity defenses. 52 F.3d 1043, at 1049-1052 (1995) (Judge Mayer dissenting). Novopharm's Petition for Rehearing with a Suggestion for Rehearing In Banc—raising the issues it presses here—was denied without dissent. (A. 59a-60a).

COUNTER STATEMENT OF FACTS

A. United States Patent No. 4,521,431 In Suit And Its Infringement

The '431 patent in suit covers a particular, newly created crystalline polymorphic[3] form ("Form 2") of the *per se* previously known chemical molecule ranitidine hydrochloride. Form 2 ranitidine hydrochloride was invented by a Glaxo chemist Dr. Derek Crookes. The patented Form 2 polymorph is the active drug substance in a medicine sold under the trademark "Zantac"®, used to treat conditions relieved by lowering gastric acidity. Its main use is for treatment of gastric and peptic ulcers. There are other substantial medical indications. The drug functions as an H_2-antagonist; i.e., it inhibits the histamine-induced secretion of gastric acid in the stomach. Claims 1 and 2 of the '431 patent are specific to the Form 2 ranitidine hydrochloride polymorph active drug substance.

Novopharm filed an Abbreviated New Drug Application ("ANDA") seeking the approval of the Federal Food and Drug Administration to market Form 2 ranitidine hydrochloride on December 5, 1995 - before the '431 patent expires. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This is a statutory act of patent infringement. 35 U.S.C. § 271(e)(2)(A).

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[3] Certain crystals can exist with their constituent repeating chemical molecules arranged in the crystalline lattice in different ways. Each such different crystalline structure is called a "polymorph".

Novopharm admitted infringement of claims 1 and 2 of the '431 patent by formal Rule 36 Fed.R.Civ.P. judicial admission.

B. The Azeotrope Granulation "Best Mode" Facts

Novopharm's best mode defense was withdrawn from presentation of evidence by the District Court at the conclusion of petitioner's case in response to Glaxo's motion to dismiss under Rule 52(c), Fed.R.Civ.P. (Please see, p. 3-4, *supra*). We thus discuss the limited trial facts Novopharm presented on point - and what was lacking in its presentation.

a. Substantive Matters

(i) The Trial Evidence On "Best Mode"

The application leading to the '431 patent was filed and prosecuted for years with only two claims, the claims ultimately issuing as claims 1 and 2 of the patent in suit.[4] These are both for the Form 2 ranitidine hydrochloride active drug substance (only). The sole inventor of the claimed Form 2 ranitidine hydrochloride was Dr. Derek Crookes who discovered it.

When the application was filed, some scientists at Glaxo (only Mr. Collin is identified in the record) knew of an azeotrope granulation process which was preferred when ranitidine hydrochloride was formulated into tablets with various excipients.[5]

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[4] Claim 2 was originally independent. It was amended during prosecution to depend from claim 1.

[5] Ranitidine hydrochloride is a relatively light material ("low bulk density"). When the material was given to the Glaxo Pharmacy Department, Glaxo scientists in that Department charged with combining the ranitidine hydrochloride with various fillers, binders and carrier, to form commercial products chose an azeotroping process to granulate the active drug substance (granulation in one way or another is common to most tableting processes and has been for years). This process increased the bulk density of the material, making it easier to dispense the active ingredient accurately when manufacturing tablets.

Mr. Graham Brereton, the Glaxo U.K. corporate patent staff member who initially worked on patenting the Form 2 invention at Glaxo, knew of the azeotrope granulation process. So did the United Kingdom Chartered Patent Agent who corresponded with Mr. Brereton, Mr. Marchant of the firm of Elkington & Fife, who was responsible for worldwide international patent filings for the Form 2 subject matter.

Messrs. Brereton and Marchant reasoned that there would be no best mode problem in the United States with respect to claims to the Form 2 ranitidine hydrochloride active ingredient *per se* if azeotrope granulation was not disclosed in the application leading to the '431 patent. They assumed that there would be a problem if pharmaceutical preparations (e.g., tablets) were claimed. They did not have in mind the United States requirement for knowledge by the *inventor* before a best mode issue arises. No United States attorney was consulted on the subject.

This all proceeded without the knowledge or participation of the inventor Dr. Crookes. The *only* evidence in this record is that Dr. Crookes simply did not know of the azeotrope-granulation process.

(ii) Factual Areas Not Treated By Novopharm's "Best Mode" Trial Evidence

There is nothing in the trial record to suggest any involvement or knowledge of inventor Crookes in the field of pharmaceutical formulation for any purpose, and certainly not for the formulation of administrable medicines from the Form 2 ranitidine hydrochloride active drug substance.[6] Rather, Dr. Crookes was charged with replicating chemical batches of the ranitidine hydrochloride active ingredient, and with developing a chemical recrystallization process. Both of these

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[6] Pharmacy—the art and science of processing active drug substances, stabilizers, buffers, and other excipients into administrable medicines—is a recognized field unto itself, with its own professional associations, journals and the like.

responsibilities *ended* when the active drug substance was created, leaving to others of another technical discipline the task of formulating the ranitidine hydrochloride raw chemical into administrable products.

There is nothing in the record from which the District Court as trier of fact could conclude that Dr. Crookes had any role in or knowledge of the azeotrope granulation process to tablet Form 2 (or any form) of ranitidine hydrochloride. The District Court found there was no evidence from which to find such knowledge reposing with Dr. Crookes. (A. 56a). The Federal Circuit agreed. (A.16a).

There is also no evidence in the record - none - of any attempt or plan to isolate or freeze out Dr. Crookes from knowledge or participation with tableting. Indeed, Dr. Crookes had left ranitidine work for other responsibilities before the United States filing was being prepared or prosecuted.

We note the above facts presented in petitioner Novopharm's case at trial—not from Glaxo's case at trial. The reason, again, is that the "best mode" defense was withdrawn under Rule 52(c) before Glaxo would have been called upon to respond.

b. Novopharm's Belated Discovery Attempts

This litigation began with Novopharm pleading an affirmative "best mode" invalidity defense. Novopharm then decided not to pursue it, electing instead to proceed on a "streamlined", anticipation-only basis to reach trial before Genpharm. This strategy changed, however, with the recognition that its chosen anticipation defense came a cropper. (Please see, p. 3, *supra*).

On *June 2*, 1993 - over two months before trial - Novopharm received *all* of the documents upon which it relied for the best mode defense. Novopharm complains here that it was wrongfully denied the deposition of Dr. Crookes

on the best mode defense. The reason it was denied the deposition was that Novopharm didn't ask for it in a timely, or anything like a timely, manner; and Novopharm didn't notice the deposition in a proper forum.

This case had long been set for trial beginning August 9, 1993. Novopharm had made several attempts to adjourn the trial, which were denied. It was clear under North Carolina practice and District Court Judge Boyle's rulings that the trial date was real.

The *August 9th* imminent trial date notwithstanding, Novopharm did not notice Dr. Crookes' deposition until *August 5-7*, 1993. That is literally the weekend before trial was to begin. Rather than seek such discovery after receiving the documents it relies upon for its best mode defense, Novopharm had proceeded by motion for summary judgment on best mode grounds without having any information that Dr. Crookes had knowledge of the "best mode". Instead, Novopharm chose to proceed on its theory that "best mode" knowledge of others at the corporate assignee Glaxo sufficed for a best mode defense . Moreover, when Novopharm finally did request Dr. Crookes' deposition, Novopharm noticed Dr. Crookes, a resident of the United Kingdom, for deposition in Elizabeth City, North Carolina.[7,8] Elizabeth City, North Carolina is far more than 100 miles from the U.K. The Notice was urged to be improper under Rules 26(a), 34(b) and 45(c)(3)(A)(ii), Fed.R.Civ.P. The Notice was served days after the District Court had already denied Novopharm's frenetic attempts to obtain the compulsory presence in North Carolina

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[7] During the years of discovery, Glaxo had voluntarily produced *all* prior witnesses requested by Novopharm in New York at the offices of Glaxo's trial counsel.

[8] Only Novopharm can speak to why it waited until the weekend before trial to notice Dr. Crookes, and violated the Rules in choosing the forum. Our belief is that the clear purport of the Declaration Dr. Crookes submitted opposing Novopharm's motion for summary judgment on best mode grounds demonstrated to Novopharm that there was little prospect that such a deposition would be useful.

of other Glaxo U.K.-based employees on the same Rule 45 grounds. The District Court denied Novopharm's efforts to compel this discovery.

ARGUMENT

Point I. There Was No Best Mode Violation

(i) Novopharm's Best Mode Defense Lacks Merit—And There Was No Failure Of Procedural Due Process

"Best mode" is an issue of fact. *Amgen, Inc.* v. *Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1209 (Fed. Cir. 1991), *cert. denied*, 112 S.Ct. 169, 116 L.Ed.2d 132 (1991). Petitioner Novopharm had the burden of proving the facts of this affirmative defense - and proving it by clear and convincing evidence. *Scripps Clinic & Research Foundation* v. *Genentech, Inc.*, 927 F.2d 1565, 1578 (Fed. Cir. 1991); *Engel Industries, Inc.* v. *Lockformer Co.*, 946 F.2d 1528, 1531 (Fed. Cir. 1991).

During Novopharm's case-in-chief at trial, it produced *no* evidence (much less clear and convincing evidence) from which the District Court could conclude that Dr. Derek Crookes, the *inventor* of U.S. Patent No. 4,521,431 in suit, knew of the azeotroping process used during the formulation of the ranitidine hydrochloride active drug substance into tablets, or any special benefits of that process. (See, pp. 6-7, *supra*). Accordingly, the District Court correctly concluded that it could not "find as a fact Crookes knew azeotroping was the preferred mode or attempted to conceal such preferred mode in the '431 patent application."[9] 830 F.Supp. 871, at 881

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[9] Novopharm's only basis for claiming the finding was clearly erroneous is that knowledge by Crookes of azeotrope granulation at the time of filing should be inferred because others at Glaxo had such knowledge. There is absolutely no basis for this inference, and the trial court correctly refused to make it.

(1993). The Federal Circuit agreed. (A.16a). Petitioner Novopharm also failed to produce *any* evidence (much less clear and convincing evidence) of any purposeful scheme at Glaxo to isolate or freeze Dr. Crookes out of knowledge concerning the azeotrope granulation process or its benefits.

Novopharm urges that the record is devoid of evidence of Dr. Crookes' knowledge of the best mode because Glaxo and the District Court improperly denied Novopharm discovery on the issue. However, Novopharm's deposition discovery attempt was belated because Novopharm had dropped the defense after having pleaded it at the very beginning of the case; the discovery attempt was belated because Novopharm pursued summary judgment on its erroneous assumption that Glaxo's corporate knowledge sufficed for "best mode" purposes without also pursuing discovery on Dr. Crookes' knowledge; and when Novopharm finally attempted to obtain a deposition on the eve of trial, the discovery attempt was improper under Rules 26(a), 34(b) and 45(c)(3)(A)(ii) because the situs chosen for the deposition was improper.[10] (Please see, pp. 3-4, 8-9 *supra* regarding Novopharm's tactical summary judgment choice and attribution argument, and its eve-of-trial shift of approach.) This out-of-time, out-of-place discovery was properly denied by the District Court. Novopharm makes no showing that it was an abuse of discretion, much less a denial of due process.[11]

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[10] *Farmer* v. *Arabian American Oil Co.*, 379 U.S. 27, 231-32, 13 L.Ed.2d 248, 85 S.Ct. 411 (1964); *St. Paul Fire & Marine Insurance Company* v. *Royal Insurance Company of America*, 1993 U.S. Dist. LEXIS 9415 (S.D.N.Y. July 9, 1993); *Brockton Savings Bank* v. *Peat, Marwick, Mitchell & Co.*, 771 F.2d 5, 10 (1st Cir. 1985), *cert. denied*, 475 U.S. 1018, 106 S.Ct. 1204, 89 L.Ed.2d 317 (1986); *Cleveland* v. *Palmby*, 75 F.R.D. 654 (W.D.Ok. 1977); *Smith* v. *Bic Corp.*, 121 F.R.D. 235, 245 (E.D.Pa. 1988), *aff'd. in relevant part*, 869 F.2d 194 (3rd Cir. 1989); *Hecht* v. *Don Mowry Flexo Parts, Inc.*, 111 F.R.D. 6, 11 (N.D.Ill. 1986).

[11] *Serrano-Perez* v. *FMC Corp.*, 985 F.2d 625, 627-28 (1st Cir. 1993); *Folmar* v. *American Health and Life Ins. Co.*, 91 F.R.D. 22, 25-26 (E.D.Tenn. 1981); *Havee* v. *Belk*, 775 F.2d 1209, 1223 (4th Cir. 1985).

Following Novopharm's evidence, the District Court withdrew the best mode defense after Glaxo's motion to dismiss under Rule 52(c), and there was no presentation by Glaxo on the point.

(ii) The Statute Is Clear; Means What It Says; And Requires The Best Mode Be Known To The Inventor - There Was No Best Mode Violation

The patent statute requires that the patent application specification "set forth the best mode contemplated by the *inventor* of carrying out his invention" (emphasis added) (See the first footnote on page i, *supra*.). A litany of authority prior to this case made clear that a best mode analysis addresses *only* the subjective knowledge of the inventor. *Texas Instruments Inc.* v. *U.S. Int'l. Trade Com'n*, 871 F.2d 1054, 1061 (Fed. Cir. 1989); *Chemcast Corp.* v. *Arco Industries Corp.*, 913 F.2d 923, 927-28 (Fed. Cir. 1990); *Engel Industries, Inc.* v. *Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991); *Amgen, Inc.* v. *Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1209-10 (Fed. Cir. 1991); *Spectra-Physics, Inc.* v. *Coherent, Inc.*, 827 F.2d 1524, 1532 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 954, 108 S.Ct. 346, 98 L.Ed.2d 372 (1987); *Hewlett-Packard Co.* v. *Bausch & Lomb Inc.*, 722 F.Supp. 595 (N.D.Cal. 1989), *aff'd.*, 909 F.2d 1464 (Fed. Cir. 1990); *Studiengesellschaft Kohle* v. *Eastman Kodak Co.*, 616 F.2d 1315, 1340 (5th Cir. 1980), *cert. denied*, 449 U.S. 1014, 101 S.Ct. 573, 66 L.Ed.2d 473 (1980); *Honeywell Inc.* v. *Minolta Camera Co. Ltd.*, 1991 U.S. Dist. LEXIS 4222 (D.N.J. 1991); R.L. Harmon, *Patents and the Federal Circuit*, 2nd Edition, § 3.53 (BNA 1991); K. Adamo, "What's Better, What's Best - The Best Mode Requirement in US Patent Practice", *Journal of Patent & Trademark Office Society*, November 1991, pp. 814-815.

The Federal Circuit Opinion in this case concurred with this body of settled law, noting that "the statutory language could not be clearer". (A.13a). The Court below reinforced this

view by tracing the requirement for knowledge by the *inventor* in prior Patent Acts (A. 13a); in the official Commentary on the New Patent Act, 35 USCA 1, 25 (1954) (A.13a); and in an extensive line of cases requiring the subjective intention of an *inventor* to conceal a "best mode" before a violation occurs. (A. 13a-16a).

The operative rule of law has been decided and consistently applied - and accords with the language of the statute which Congress has adopted.[12] We respectfully urge that the law requires judgment for Glaxo on the issue for failure of proof of knowledge by the inventor Crookes[13], and that the District Court and Court of Appeals were correct.

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[12] Novopharm's Petition cites *CPC International, Inc.* v. *Archer Daniels Midland Company*, Nos. 94-1045, 94-1060 (Fed. Cir. July 11, 1994) (A. 59a-69a) as its only supposed substantive authority in disagreement with all of this. *CPC* was a *per curiam* affirmance (the day following oral argument) where the prevailing accused infringer pressed six bases for affirmance of the decision in its favor below. The *CPC* affirmance was designated non-precedential under the Federal Circuit's Rule 47.6(d). 31 F.3d 1176 (Fed.Cir. 1994). That Rule cautions that "opinions and orders so designated shall not be employed or cited as precedent". Novopharm ignored that Rule when repeatedly urging *CPC*, unsuccessfully, before the Federal Circuit; and ignores the Rule here. There is no division in the Federal Circuit regarding the requirement for inventor's knowledge—there was no dissent in the denial of Novopharm's suggestion for a rehearing *in banc* on the issue presented by *CPC*.

[13] Petitioner Novopharm's attempt to raise a negative inference from the fact that Derek Crookes did not testify at the trial on "best mode" should be rejected. As Glaxo had previously advised the Court, Glaxo had intended to call Dr. Crookes during its rebuttal case on the best mode issue, but the issue was withdrawn before Glaxo's rebuttal case began. Negative inferences cannot be drawn when, as was the case here, there is no *opportunity* to offer testimony. *Cf. Savard* v. *Marine Contracting Inc.*, 471 F.2d 536, 542 (2d Cir. 1972), *cert. denied*, 412 U.S. 943, 93 S.Ct. 2778, 37 L.Ed.2d 404 (1973) (no inference where evidence not within party's control) 2 Wigmore, Evidence § 290 p. 218-219 (Chadbourne rev. 1979) (until proponent has proven its case, failure to produce evidence cannot afford any inference). Moreover, inferences, negative or otherwise, do not suffice for even a *prima facie*, much less a clear and convincing, case. *Layne* v. *Vinzant*, 657 F.2d 468, 472 (1st Cir. 1981); *El*

Point II. There Was No Denial Of Due Process Concerning The Crookes Declaration

As part of its opposition to petitioner Novopharm's motion for summary judgment before the District Court, Glaxo submitted a Declaration of inventor Crookes that he was not aware of the "best mode" azeotrope granulation process. (See, pp 6-7 *supra*; the Crookes Declaration is reproduced in a Supplemental Appendix, attached to this Brief.) Novopharm's thesis in its Petition is that the Federal Circuit denied Novopharm due process in referring to the Crookes Declaration (A.16a).

There was no due process violation regarding the Crookes Declaration by the District Court. The District Court reviewed the evidence submitted by Novopharm during its opposition case-in-chief. The Court noted that the "only evidence Novopharm presented on its best mode defense was the testimony of Graham George Brereton and concluded that there was *no* evidence that Dr. Crookes was aware of the best mode azeotrope granulation process. The trial judge made *no* mention of the Crookes Declaration and it formed no part of his decision.

There was similarly no due process violation by the Federal Circuit. The Courts of Appeals review judgments below for error, *Torrington Co.* v. *Local Union 590 of Int'l. Union*, 803 F.2d 927, 932 (7th Cir. 1986); *Worsham* v. *Duke*, 220 F.2d 506, 509 (6th Cir. 1955), and the District Court could not have committed error since it did not in any way refer to the Crookes Declaration in its decision making process.

For its part, the Federal Circuit's affirmance rested upon the failure of Novopharm to sustain its burden of proving the

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Ranco Inc. v. *First National Bank of Nevada*, 406 F.2d 1205, 1215 (9th Cir. 1968), *cert. denied*, 396 U.S. 875 (1969); *United States* v. *Roberson*, 233 F.2d 517, 519 (5th Cir. 1956). The District Court and Court of Appeals were invited by Novopharm to make the negative inference, but correctly decided not to do so.

supposed "best mode" defense, not on Glaxo's demonstrating that the defense lacked merit, and it was not Glaxo's burden to do so. The Court of Appeals Opinion found that the statutory language (35 U.S.C. § 112, first paragraph) "could not be clearer" that a best mode inquiry is directed to the knowledge of the *inventor* (A. 12a-15a) and then applied the law to the trial evidence:

> There is simply no evidence in the record before us, indeed Novopharm points to none, that the inventor of the '431 patent knew of and concealed the azeotroping process when his application was filed.[14] (A. 16a).

The District Court's rejection of the best mode defense was affirmed on this basis. Accordingly, there was no due process violation here.

* * *

Indeed, it is at least curious that *Novopharm* even raises here the propriety of the Federal Circuit's discussion of the Crookes Declaration (as they also did unsuccessfully with the Federal Circuit upon Petition for Reconsideration). The Crookes Declaration disclaiming knowledge of azeotrope granulation was raised to the Federal Circuit by *petitioner Novopharm*. Page 27 of *Novopharm's* Brief on Appeal below made reference to the Declaration and pejoratively characterized it as an "evasive affidavit [sic]". Novopharm's Reply Brief (page 5) also discussed the Declaration. Novopharm should not be heard to complain that the Federal Court's Opinion (A. 16a.) disagreed with Novopharm on a matter *it* chose to bring into the Appeal. The Court of Appeal's reading of the Declaration that Dr. Crookes did not know of azeotrope granulation (unlike the way *Novopharm* had characterized it

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[14] Even at this belated point in the proceedings Novopharm does not point to any record evidence that Dr. Crookes knew of the azeotrope granulation process.

in its opening Brief on appeal) in any event is not a necessary part of its affirmance.[15] As explicitly observed by both the Federal Circuit and the District Court, Novopharm failed on its best mode defense because it failed in *its* burden of proving that Dr. Crookes knew of the process.[16]

CONCLUSION

For the reasons stated above, Respondents Glaxo, Inc. and Glaxo Group Limited respectfully urge that Novopharm's Petition for Writ of Certiorari be denied.

Dated: October 19, 1995

Respectfully submitted,

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[15] If it mattered, the *only* record evidence on Dr. Crookes' knowledge of the azeotrope granulation process is that he did not know. (A. 56a).

[16] We also note that the azeotrope granulation process for making tablets is not invoked as any part of the manufacture of the Form 2 ranitidine hydrochloride which is the subject of claims 1 and 2. Even *had* Dr. Crookes known of this subject matter, Glaxo urges that there would be no best mode violation of these claims. The issue was expressly reserved in footnote 7 of the Federal Circuit's Opinion. (A. 16a)

APPENDIX

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
RALEIGH DIVISION

Civil Action No. 91-759-CIV-5-B0

GLAXO INC. and GLAXO GROUP LIMITED,

Plaintiffs,

—v.—

NOVOPHARM LTD.,

Defendant.

DECLARATION OF DR. DEREK CROOKES IN OPPOSITION TO DEFENDANT NOVOPHARM'S MOTION FOR SUMMARY JUDGMENT ON SUPPOSED BEST MODE PATENT INVALIDITY GROUNDS

I, Derek Crookes, a British subject and a resident of the United Kingdom, declare upon knowledge, information and belief as follows:

1. I am employed by Glaxo Group Research, an affiliate of Glaxo Group Limited, a co-plaintiff in this litigation. I am the sole inventor of United States Patent No. 4,521,431. I was awarded a Ph.D degree in Chemistry in 1978 by Manchester University.

2. I joined Glaxo as a member of its Chemical Development Department in 1978. I worked on the preparation of ranitidine hydrochloride at Glaxo between September 1979 and November 1980, and not thereafter, with the sole exception of my

involvement with this litigation after its commencement in 1991.

3. Before I joined the ranitidine hydrochloride project in September, 1979, and prior to any work by me, the earlier crystalline form of ranitidine hydrochloride (now called Form 1) had already been synthesized as of 1977; and the generic ranitidine hydrochloride molecule had been patented (United States Patent No. 4,128,658 issued December 5, 1978).

4. Beginning in September 1979, part of my assigned responsibility was to produce batches of bulk ranitidine hydrochloride to serve as an active drug substance. The material which I initially produced was of the crystalline form now known as Form 1 ranitidine hydrochloride. I was also charged with the identification and scale-up of possible alternative synthetic routes which might lead to the Form 1 ranitidine hydrochloride active drug substance.

5. The bulk active material I produced was provided to Glaxo's Pharmacy Department. Pharmacy's job, in turn, was to formulate the ranitidine hydrochloride active ingredient into medicinal products; i.e., to develop methods to process the ranitidine hydrochloride active drug substance and various excipients into medically administrable tablets, syrups, injectables and other formulations. Pharmacy supplied yet further groups such as Glaxo's Pathology and Clinical Departments with their requirements of formulated product for whatever testing they deemed appropriate.

6. On April 15, 1980, without prior intention to do so, I invented the Form 2 polymorph of ranitidine hydrochloride while preparing a batch of ranitidine hydrochloride known as 3B13. By inspection I judged the ranitidine hydrochloride material prepared in batch 3B13 to be different from earlier batches. Both infra-red and x-ray powder diffraction measurements were made of the ranitidine hydrochloride I made in batch 3B13. Each of these measurements confirmed that I had prepared a different crystalline polymorph which has now come to be known as Form 2 ranitidine hydrochloride.

7. Several hundreds of kilograms of ranitidine hydrochloride (Form 1) had been processed by the Pharmacy Department prior to my invention of the Form 2 polymorph of ranitidine hydrochloride on April 15, 1980. I produced ranitidine hydrochloride active drug substance (either Form 1 or Form 2) as required from time to time in batches of approximate size 20 to 60 kilograms, and supplied the active drug substance to Pharmacy.

8. As I viewed matters - both when I was active on the ranitidine hydrochloride project in 1979-1980, and currently - Pharmacy Department's work, skills and knowledge were different from mine; and their responsibilities were different from mine.

9. I - the inventor of the subject matter underlying U.S. Patent No. 4,521,431 - did not participate in the development of the process or processes by which the active drug substance Form 2 ranitidine hydrochloride was processed with excipients into administrable medicine of any form. I did not know of any azeotroping of ranitidine hydrochloride, or of its benefits, prior to commencement of this litigation. I did not—indeed, could not—consider the azeotrope process a "best mode" of making ranitidine hydrochloride tablets at the time of filing any patent application. I did not—indeed, could not—consider azeotroping the best mode of carrying out my invention at any time while the '431 patent was pending.

10. I knew that Pharmacy was using a granulation process to make tablets from the ranitidine hydrochloride active drug substance I provided to them. It was my understanding in 1979-1980 - and it is my understanding now - that granulation is a process used when formulating tablets from a great many, perhaps most, active drug substances. I did not know the specific details of the granulation process or processes to which Pharmacy put ranitidine hydrochloride. At all times prior to this litigation, I believed that whatever granulation process or processes Pharmacy was using were simply conventional. I believed that the process or processes did not differ from

conventional granulation, or give rise to any benefit not common to conventional granulation.

11. I have been advised that patent applications were filed on the azeotrope process for ranitidine hydrochloride. I did none of the work which underlies those patent applications; I was not an inventor or co-inventor of that work; I did not know of that work until after this litigation commenced.

I declare further that all statements made herein to my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: July 8, 1993

/s/ DEREK CROOKES
Dr. Derek Crookes

Supreme Court, U.S.
FILED
NOV 22 1995
OFFICE OF THE CLERK

(3)

No. 95-477

In The

Supreme Court of the United States

October Term, 1995

NOVOPHARM LTD.,

Petitioner,

v.

GLAXO, INC. and GLAXO GROUP LIMITED,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY TO BRIEF IN OPPOSITION

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REPLY TO BRIEF IN OPPOSITION

A. Novopharm Did Everything Possible To Obtain Best Mode Discovery

Glaxo's "facts" regarding the inability of Novopharm to obtain any meaningful pre-trial discovery on the best mode issue are replete with errors. Novopharm did everything possible to obtain that discovery, but was thwarted by Glaxo, and denied relief by the district court. Glaxo, at pages 6-9 of its brief, portrays Novopharm's discovery efforts as fumbling, eleventh-hour acts of desperation, which were properly denied by the district court. Nothing is further from the truth.

Glaxo states that Novopharm received the documents upon which Novopharm was forced to rely for its best mode defense on June 2, 1993. That much is true. Glaxo then argues that Novopharm waited until the eve of trial to attempt to get discovery on the best mode issue, and thus was rightly denied that discovery. That is simply untrue.

As stated previously in Novopharm's Petition, on June 21, 1993, Novopharm filed a motion for summary judgment of invalidity due to Glaxo's violation of the best mode requirement, in which Novopharm asked for discovery on the issue in the event the court was inclined to deny the motion. In response, Glaxo vigorously disputed, *inter alia*, Novopharm's right to bring the motion, insisting that best mode should not be an issue in the lawsuit. While the summary judgment motion was pending, Novopharm attempted to obtain deposition testimony from Mr. Collin, the supervisor of the named inventor, Dr. Crookes, regarding the best mode issue, but was

frustrated in its efforts by Glaxo. (SA 9-14).[1] Therefore, Novopharm had no way to obtain the discovery it desired without intervention from the district court.

On July 20, approximately one week after being rebuffed at the depositions, Novopharm asked the district court to inform Glaxo that best mode was a part of the lawsuit, and that Novopharm was entitled to discovery. Rather than deciding the issue then, with trial fast approaching, the district court took the question under advisement until the pre-trial conference of July 28, 1993, where it ruled that the best mode issue would be tried. The very next day, July 29, 1993, and not August 5, 1993, as Glaxo states (Resp. Br. 8),[2] Novopharm served notices of deposition for Dr. Crookes and Mr. Collin, as well as document requests.

Glaxo attacks Novopharm's attempted discovery as being violative of a host of rules, including that the depositions of Collin and Crookes were noticed for North Carolina. (Resp. Br. 8-9). This argument is irrelevant at best. Novopharm did notice the Crookes and Collin depositions for North Carolina, but did so for a very good reason. At the designated deposition date, counsel for both Glaxo and Novopharm would be in North Carolina preparing for trial. Dr. Crookes and Mr. Collin were also

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[1] References to "SA___" are to the supplemental appendix, which is attached hereto. SA 1 through SA 4 are found in Respondent's Brief in Opposition to Petition for a Writ of Certiorari.

[2] References to "Resp. Br. ___" are to the Respondent's Brief in Opposition to Petition for a Writ of Certiorari.

expected to be in North Carolina, as they were designated by Glaxo as trial witnesses.

Given these facts, the district court erred in denying Novopharm any discovery on the best mode issue, as did the Court of Appeals for the Federal Circuit in affirming that denial. The fact that Novopharm was forced to move quickly on the best mode issue at a time close to the scheduled trial date did not result from any failure on its part. Instead, it resulted from the fact that the district court did not rule on Novopharm's motion to compel until April 27, 1993, *nine months* after the motion was filed, coupled with foot-dragging by Glaxo in producing the documents. Until those improperly withheld documents were received, Novopharm had no basis to even suspect a best mode violation. The district court's refusal to allow any discovery on the best mode issue, and the Federal Circuit's affirmance, penalizes Novopharm for things beyond its control, and is error.

B. Glaxo Affirmatively Chose Not To Present The Testimony Of Dr. Crookes At Trial

With the denial of Novopharm's discovery efforts, the stage was set for trial. There, despite the fact that Novopharm had been allowed no discovery on the best mode issue, Novopharm showed the following, which was adopted by the district court and is not disputed by Glaxo: that (1) Mr. Brereton, Glaxo's in-house patent agent in charge of its Form 2 applications, (2) Mr. Marchant, Glaxo's outside patent agent, and (3) numerous scientists within Glaxo, including Mr. Collin, Dr. Crookes' direct supervisor, knew of Glaxo's best

mode azeotrope granulation technique prior to the filing date of both Glaxo's British and U.S. Form 2 applications. (53a-54a, 56a-57a).

This unequivocal evidence, coupled with Glaxo's failure to allow Crookes, *still a Glaxo employee*, to testify at trial, should have mandated an inference that Crookes also knew. Crookes' absence from the trial was particularly suspect, as he was a designated trial witness *until* Novopharm made the best mode violation an issue for trial.

Glaxo argues that the district court was correct in not inferring knowledge to Crookes, because Glaxo, *Crookes' employer at the time of trial*, did not have the opportunity to present evidence on the best mode issue. Glaxo states that it did not call Crookes to testify because the district court withdrew the best mode issue from the case at the close of Novopharm's case-in-chief. (Resp. Br. 3-4, 12 n.13). Again, this is simply not so.

Glaxo did have an opportunity to present the testimony of Dr. Crookes at trial. The district court only withdrew the best mode issue from the case after Glaxo's lead trial counsel told the district court that Glaxo had nothing to add on that issue. The following interchange is illuminating:

> THE COURT: At the risk of extending this hearing further, I want to ask you a serious question about best mode. If the motion to enter judgment under Rule 52 was denied on best mode, there really isn't anything further that you would put on factually, is there?

* * *

> MR. JUDLOWE: . . . We depending on the dynamics I suppose, make a decision whether we gain anything by putting Dr. Crookes on the stand to repeat it, but I'm not so sure that there's anything of value that would be gained from that.

(SA 7-8).

The above exchange clearly shows that had Glaxo told the district court that Glaxo wanted to have Dr. Crookes testify, the district court would not have withdrawn the best mode issue from the case. Thus, Glaxo did have the opportunity to present Dr. Crookes' testimony at trial, yet made a conscious decision not to do so. The cases cited by Glaxo in its brief (page 12 n.13) are clear that in this situation, the district court could have drawn the inference that Crookes' testimony would have been unfavorable to Glaxo. *Savard v. Marine Contracting, Inc.*, 471 F.2d 536, 541 (2d Cir. 1972), *cert. denied*, 412 U.S. 943 (1973). The district court not only could have made this inference, it should have.

C. The Crookes Declaration Was Essential To Both The District Court's And Federal Circuit's Decisions

Next, Glaxo argues that the non-evidence Crookes Declaration played no part in the decision by the district court to find no best mode violation, or in the Federal Circuit's affirmance of that decision. (Resp. Br. 13-15). Once again, this is simply not so.

The district court, in finding no knowledge on the part of Crookes, credited the testimony of Brereton, who testified, based solely on his reading of the Crookes Declaration, that he did not believe Crookes knew. (56a, SA 5). The testimony on this point is clear and unequivocal:

> Q. Mr. Brereton, to the best of your knowledge, did Derek Crookes have any knowledge of the [best mode]?
>
> A. At the time of this . . . the filing of this case I believe not, *based on his affidavit.*

(SA 5).

The "affidavit" referred to by Mr. Brereton is the Crookes Declaration. Brereton had no other reason for this "belief," because, as he admitted, he had never at any time discussed the best mode issue with Dr. Crookes. (SA 6).

The district court, equally clearly, relied on Brereton's "belief", gained from the Crookes Declaration: "Brereton testified . . . it was his belief that Crookes did not know . . . . " (56a). The district court, by crediting Brereton's testimony on the issue of Crookes' knowledge, therefore improperly gave weight to the Crookes Declaration, without hearing from Crookes himself, without the Declaration being in evidence, and without giving Novopharm any opportunity to test the merits of that Declaration through either discovery or cross-examination. This is clear error.

Thus, Novopharm took this issue to the Court of Appeals for the Federal Circuit, assuming that the district court's use of the non-evidence Crookes Declaration would be condemned. On the contrary, the Federal Circuit embraced the Crookes Declaration, making it the

centerpiece of its affirmance of the district court on the best mode issue, thereby violating Novopharm's right of due process.

Glaxo's argument that the Federal Circuit did not consider and rely upon the Crookes Declaration borders on the ridiculous. The Federal Circuit majority *quoted* from the Declaration (16a), and the Declaration provided the only support for statements by the majority in its opinion, such as the following:

> Crookes was unconcerned with the commercialization of the claimed compound. It is undisputed that Crookes invented a compound and was not involved in whatever process were to be used to commercially produce it.

(17a). These "facts" come only from the Declaration. (SA 1-4).

Thus, both the district court and the Federal Circuit relied on the non-evidence Crookes Declaration. Glaxo is wrong when it argues to the contrary.

D. Novopharm Was Denied Due Process

To summarize, the following is the scenario that befell Novopharm in the district court and the appellate court. Novopharm, approximately two months before trial, received documents from Glaxo that Novopharm had been seeking for over nine months. Within three weeks of receiving the documents, Novopharm filed a motion for summary judgment on the best mode issue, alternatively asking for discovery. During the pendency of that motion, Glaxo refused Novopharm any discovery on the best mode issue, even directing its deposition

witnesses to not answer any questions related to best mode. The district court then denied Novopharm any discovery on the best mode issue.

At the trial, Novopharm proved that numerous persons at Glaxo, including the patent agent responsible for the application, and Dr. Crookes' supervisor, knew of the concealed best mode. Glaxo then withdrew Crookes from its witness list, and informed the district court that Glaxo would not present any witnesses on the best mode issue.

The district court then found for Glaxo on the best mode issue, stating that Novopharm had failed to prove Crookes knew, relying on Brereton's testimony about the non-evidence, untested Crookes Declaration. On Appeal, the Court of Appeals for the Federal Circuit affirmed, also relying on the Crookes Declaration.

The result of the above is to deny Novopharm its right of due process, and even more importantly, to deny Novopharm the sense that it has been treated fairly and has received "justice" from the court system. If litigants lose confidence that the system works and is fair, the system itself will fail. That is precisely why the safeguards of due process, such as the right of cross-examination, are so important, and so fundamental to our system of justice. Novopharm respectfully asks this Court to recognize those safeguards, which have been ignored by

the district court and the Court of Appeals for the Federal Circuit.

Respectfully submitted,

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* * *

[p. 548] A Yes, it is.

Q And that patent, as it issued, contains claims to pharmaceutical compositions of ranitidine hydrochloride, doesn't it?

A Yes, it does.

Q Specifically claims tablets and other things?

A That's correct.

Q Isn't that true?

A Yes.

Q Now, looking through the specifications of this patent, is this granulation technique disclosed anywhere in the '431 patent?

A No, it's not.

MR. WARD: I have nothing further, Your Honor.

THE COURT: Any cross?

MR. LOCKMAN: Very brief, Your Honor.

CROSS-EXAMINATION

BY MR. LOCKMAN:

Q Mr. Brereton, to the best of your knowledge, did Derek Crookes have any knowledge of the – granulation program Mr. Ward was questioning you about?

A At the time of this – the filing of this case. I believe not, based on his affidavit.

Q And did you at any time ever intend to

* * *

[p. 553] Honor.

THE COURT: All right.

THE WITNESS: Oh, sorry.

THE COURT: Just one second.

THE WITNESS: I'm sorry.

MR. WARD: I'll let you go very soon.

REDIRECT EXAMINATION

BY MR. WARD:

Q At the time the initial British specification was filed for Form 2 ranitidine hydrochloride, prior to that time, had you or anyone else at Glaxo investigated what Dr. Crookes knew about this granulation technique?

A I'm sorry, could you repeat the time frame?

Q Prior to the filing of your British application on Form 2 in 1980, October 1980, did you or anyone else within Glaxo investigate what is fact Dr. Crookes did knew about this granulation process?

A No.

Q Don't you think it would have been a good idea to do that?

A I didn't appreciate that the requirement for best mode was the – the knowledge of the inventor.

Q And how do you have that appreciation today?

A Through the events of this litigation.

Q Now, at the time you believed that the

* * *

[p. 761] Telcom case they cited didn't even discuss the issue, didn't begin to discuss the question of knowledge of the inventor relative to the knowledge of the assignee. And the final case they have referred us to this morning is International Telephone and Telegraph Corporation versus United Carbide, 210USPQ496. Over the lunch hour we were able to extract a copy finding 124, it said, information – quote, information as to the process for making the capacitors beyond the quote without further ado, and quote, reference to dipping by hand, that was the issue, quote, was known to the inventors, end quote.

So in that situation, it obviously is a totally inapposite case because the inventors knew about it there was no question that the inventors not knowing about it.

THE COURT: At the risk of extending this hearing further, I want to ask you a serious question about best mode. If the motion to enter judgment under Rule 52 was denied on best mode, there really isn't anything further that you would put on factually, is there? What I'm trying to get at is, I'm not – this is not a loaded question. It's a very plain and direct question, as I hope all of my questions have been. It seems to me that the best mode issue is one that's [p. 762] going to have to be decided as a matter of law. You've – the facts are not much in dispute. Your witnesses said what they knew, and nobody has made any proof, and they have rested as

to the greater knowledge of the inventor. We're no further along factually on that now than we were at the summary judgment stage, I don't think, and if we aren't, not much of any value could be added factually. You're certainly not going to prove that your inventor knew, and if they haven't, then – and you're not going to disprove that your company knew because the evidence is uncontroverted that they knew. You have your patent man here.

And so whatever the ruling is will be a ruling of law, won't it, ultimately, on this?

MR. JUDLOWE: Your Honor, I – I mean. I don't doubt that the case is entirely – I guess – is an appropriate word. We depending upon the dynamics I suppose, make a decision whether we gain anything by putting Dr. Crookes on the stand to repeat it, but I'm not so sure that there's anything of value that would be gained from that. I don't disagree that the – I mean, I think you're absolutely right. I thing this is an issue of law at this point, and I think it's ripe for decision now. I certainly would be guided by whatever ruling you made now, if you made a ruling.

* * *

CONFIDENTIAL

THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA RALEIGH DIVISION

INDEX No. 91-759-CIV-5-BO

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GLAXO INC. and GLAXO GROUP LIMITED,

Plaintiffs,

-against-

NOVOPHARM LTD.,

Defendants.

----------x

July 8, 1993

DEPOSITION OF JOHN L. WHITE

NEWROCK/DeSIMONE
THE COURT REPORTERS
15 Park Row
New York, New York 10038
(212) 608-3300

[p. 2] July 8, 1993

Deposition of JOHN L. WHITE, taken by Defendant pursuant to 30(b)6 Notice, held at the offices of Hopgood, Calimafde, Kalil, Blaustein & Judlove, Esqs., 60 East 42nd Street, New York, New York, commencing at 11:15 a.m., before Joseph Ravenell, Jr., a Registered Professional Reporter and Notary Public of the State of New York.

NEWROCK/DeSIMONE
THE COURT REPORTERS
15 Park Row
New York, New York 10038
(212) 608-3300

* * *

[p. 8] CONFIDENTIAL – WHITE

the deposition today pending further direction from the Court on the proper scope of discovery.

Again, if the expert testimony is allowed and if Mr. Edelman offers certain opinions and we decided that we want to offer rebuttal opinions at trial from Mr. White, obviously you would have an opportunity to depose on any issues – under all those conditions, then you would have an opportunity to depose on such issues even though you won't have that opportunity today.

I hope that's clear.

MR. WARD: Let me see if I can set the ground rules as I understand it.

You will permit Mr. White to answer questions with respect to the issue of inequitable conduct, the Hunt and Collin declarations?

MR. LOCKMAN: Yes.

MR. WARD: You will not permit any questioning today on whether Glaxo failed to comply with the best mode [p. 9] requirement of Section 112?

MR. LOCKMAN: Not today. Pending further rulings from the Court.

MR. WARD: If I ask a question on that, you will advise the witness not to answer that?

MR. LOCKMAN: Today, that is correct. Pending completion of the briefing and guidance from the Court.

MR. WARD: You will also advise the witness not to answer any questions relating to public use?

MR. LOCKMAN: Yes.

MR. WARD: Is that also the case?

MR. LOCKMAN: Yes.

MR. WARD: Let me see what else I have.

MR. LOCKMAN: Okay.

MR. WARD: I think that's about it.

I understand the ground rules. It's my understanding that the best mode issues in the case, we have different

* * *

In The Matter Of:

Glaxo Inc. v Novopharm Ltd.

David T. Collin
July 15, 1993

Newrock/DeSimone – The Court Reporters
15 Park Row
New York, NY 10038
(212) 608-3300

* * *

[p. 322] COLLIN

MR. WARD: I saw your footnote, but I believe it mischaracterized the relevance. We believe what occurred in 1980 with regard to ranitidine hydrochloride is extremely relevant to the seeding issue. And we will continue to press that position. But for the time being we will not press it with Mr. Collin.

MR. LOCKMAN: Okay.

MR. WARD: While we are on the subject of things that Mr. Collin will not be answering at the deposition, I think we will at some point today run headlong into another one, and that is the issue of what we call the best mode issue, the granulation, the azeotroping granulation issue.

MR. LOCKMAN: Right.

MR. WARD: At this point in time, will you be allowing Mr. Collin to answer any questions that relate to this best mode issue?

MR. LOCKMAN: We are going to [p. 323] take the same position today. Again, you are about to file your response. You have a request for summary judgment, you have a request in the alternative for discovery. I assume the Court will be dealing with that in fairly short order in one form or another and we will comply with the Court's decision. We would like to defer that until we have the Court's guidance on it.

MR. WARD: So if I ask Mr. Collin a question which in your mind relates to best mode, you will advise him not to answer the question?

MR. LOCKMAN: You understand on the basis that I've stated –

MR. WARD: I understand your basis.

MR. LOCKMAN: – that we have objected to this in light of your representations and so forth. And I don't want to narrow what we have said in a lengthy pleading that is before the Court. And we simply await the Court's [p. 324] guidance and reaction to your papers and our response and so forth. Since that should be coming soon, we think it would be more prudent to wait and see what the Court has to say.

MR. WARD: I'm just trying to get the ground rules so we don't waste time with me asking a question that you are not going to allow him to answer and me going through the mechanics of asking him whether he will take your advice.

As long as we have the ground rules set at least for the time being, I won't delve into those areas. So we may see you again.

THE WITNESS: If it's next week I won't be very pleased.

Q. Just remember, I gave you the chance to say it now.

In the 1979 through 1981 time period or to 1981 time period –

MR. LOCKMAN: You are going through year end '80?

MR. WARD: Year end '80.

* * *